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DACE. VIA HAND DELIVERY JULY 29, 2004

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

Choi et al.

Docket No.: PB340P2

Application No.: 08/961,083

Confirmation No.: 6931

Filed: October 30, 1997

Art Unit: 1645

For: Streptococcus pneumoniae SP036

Polynucleotides, Polypeptides, Antigens and

Vaccines

Examiner: J. A. Hines

### APPLICATION FOR PATENT TERM ADJUSTMENT **UNDER 37 C.F.R. § 1.705(b)**

MS Petition Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Applicants hereby request reconsideration of the patent term adjustment (PTA) indicated on Form PTOL-85 with the Notice of Allowance mailed on May 21, 2004. In particular, no calculation of PTA under 35 U.S.C. § 154(b) was presented with Form PTOL-85, despite a Continued Prosecution Application (CPA) having been filed on December 11, 2000. Instead, a calculation of patent term extension (showing 0 days extension) was performed. A proper PTA calculation would show that this application is entitled to at least 388 days of PTA due to Office delays, as described more fully below.

This application is being timely made, as it is being submitted concurrently with the issue fee payment. The requirements of 37 C.F.R. § 1.705(b)(1) are satisfied by the Fee Transmittal Sheet enclosed herewith, authorizing payment of the fee set forth in 37 C.F.R. 1.18(e). The requirements of 37 C.F.R. § 1.705(b)(2) are satisfied by the following statements, as supplemented by the attached Exhibits.

### Eligibility for PTA

- 1. The instant application was originally filed on October 30, 1997. After extensive prosecution, a notice of allowance was mailed on February 1, 2000.
- 2. On April 27, 2000, an amendment under 37 C.F.R.§ 1.312 and substitute sequence listing in paper and computer-readable form were filed, together with a signed issue fee transmittal (form PTOL-85B) authorizing the issue fee to be paid from deposit account 08-3425. Copies of these papers, and the date-stamped return receipt postcard evidencing their receipt by the Office on April 27, 2000, are attached as Exhibit A.
- 3. On October 24, 2000, a Response to Rule 312 Communication was mailed, indicating that the amendment was disapproved because "the PTO no longer accepts 312(b) amendments." However, this Response was in error, as the amendment had been submitted concurrently with the issue fee payment, not after the date that the issue fee was paid.
- 4. On December 11, 2000, Applicants filed via facsimile a Continued Prosecution Application Request and a Petition to Withdraw Application From Issue Under 37 C.F.R. § 1.313(b)(1), together with a Fee Transmittal authorizing payment of the CPA fee, extra claims fees, and petition fee from deposit account 08-3425. As noted therein, these papers were filed to permit consideration of the erroneously disapproved amendment submitted on April 27, 2000. Copies of these papers are attached as Exhibit B.
- 5. The Office promptly granted the Petition on December 11, 2000, withdrawing the application from issue in favor of a CPA. A copy of the decision ("Decision") is attached as Exhibit C.
- 6. As a CPA was filed and entered by the Office on December 11, 2000, this application is eligible for patent term adjustment under 35 U.S.C. § 154.

### Correct PTA, Bases Therefor, and Relevant Dates

- 7. The correct PTA due under 35 U.S.C. § 154(b)(1)(A) is at least 388 days. This PTA calculation does not include any PTA that may be due under 35 U.S.C. § 154(b)(1)(B); this application has been pending for more than three years since the filing of the CPA discussed above.
- 8. The period between the day after the date fourteen months after Applicants' CPA was filed and entered (February 12, 2002) and the date of mailing of the first notification under 35 U.S.C. 132 (the Office Action mailed March 6, 2003) is 388 days. Thus, the instant application is entitled to 388 days of patent term adjustment pursuant to 35 U.S.C. § 154(b)(1)(A)(i) and 37 C.F.R. §§ 1.702(a)(1) & 1.703(a)(1).
- 9. Applicants note that the dates shown in File History screen of the PAIR system (attached as Exhibit D) for the filing of the CPA and the corresponding Express Abandonment for entry of the CPA are incorrect. More particularly, the CPA is shown as being filed on April 27, 2000, and the corresponding Express Abandonment for entry of the CPA is listed on February 5, 2002. However, both of these dates should be given as December 11, 2000, as evidenced by the Decision. *See* Exhibit C. The calculations of PTA shown herein use the correct date of December 11, 2000; if the Office determines that the CPA should be treated as filed on April 27, 2000, then 228 additional days of PTA would be due.
- 10. Other communications were mailed by the Office prior to the Office Action mailed March 6, 2003. Applicants respectfully assert that these communications do not qualify as notifications under 35 U.S.C. 132. These communications, and Applicants' responses thereto, are discussed in detail below.

### **Terminal Disclaimer**

11. The instant application is not subject to a terminal disclaimer.

### **Efforts to Conclude Processing or Examination**

- 12. After the filing of the CPA discussed above on December 11, 2000, no action was taken by the Office until January of 2002, when the Examiner contacted the undersigned and requested copies of the papers filed on April 27, 2000, and December 11, 2000, as well as a copy of the Decision. Copies of these papers were provided by facsimile to the Examiner on January 18, 2002. The Fax Cover Sheet and confirmation page are attached as Exhibit E.
- 13. The first written communication from the Office subsequent to the Decision was the Notice of Non-Compliant Amendment mailed August 9, 2002. The Notice alleged that an amendment (presumably the Rule 312 amendment filed on April 27, 2000) did not comply with 37 C.F.R. 1.121 as amended September 8, 2000. Applicants contacted the Examiner on September 9, 2002, advising her that the Amendment had been properly filed in compliance with the rules governing amendments on that date. As requested by the Examiner, Applicants filed a reply to the Notice by facsimile on September 9, 2002. Copies of the Notice and the Reply are attached as Exhibit F. Applicants note that the PAIR entry for this Reply incorrectly identifies it as a "Response after Non-Final Action," and incorrectly lists the date as September 8, rather than September 9.
- 14. On November 14, 2002, a Notice to Comply with the sequence listing requirements was mailed. The Notice stated that the computer readable form (CRF) of the sequence listing submitted with the amendment of April 27, 2000 had not been received by the Office, and required a substitute paper sequence listing, CRF, and statements regarding the content thereof. The Notice is attached as Exhibit G.
- 15. The CRF had been properly submitted and received by the Office on April 27, 2000. *See* the date-stamped return receipt postcard included in Exhibit A. Thus, the Notice to Comply with the sequence listing requirements was in error to the extent that it claimed that "no such form has been received [sic] by the office."
- 16. Despite the error in the Notice to Comply with the sequence listing requirements, Applicants filed a response providing a replacement copy of the sequence

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listing in paper and CRF, together with the required statement regarding their conduct, on December 13, 2002. Applicants also updated the formatting of the sequence listing to comply with the current sequence rules with regard to "n" nucleotides and "Xaa" amino acids for the convenience of the examiner. The previously submitted sequence listing was formatted according to the rules in place when it was filed (April 27, 2000). Copies of the response and sequence listing are attached as Exhibit H.

- Amendment mailed August 9, 2002, and the Notice to Comply with the sequence listing requirements mailed November 14, 2002, and Applicants' replies thereto, do not evidence any circumstances constituting a failure to engage in reasonable efforts to conclude processing or examination of the application as set forth in 37 C.F.R. § 1.704. As discussed above, both notices were made in error, but Applicants nevertheless replied promptly in order to allow examination to continue expeditiously. Thus, none of Applicants' filings from December 11, 2000 to the present fall within 37 C.F.R. § 1.704, and no reduction of PTA should be made.
- 18. To the extent that the papers provided by facsimile to the Examiner on January 18, 2002 could be considered a supplemental reply or other paper under 37 C.F.R. § 1.704(c)(8), Applicants point out that these papers were expressly requested by the Examiner via telephone. Thus, no reduction of PTA should be made based on this filing pursuant to 37 C.F.R. § 1.704(c)(8).
- 19. Although the amendment submitted on April 27, 2000 was made under 37 C.F.R. § 1.312, Applicants respectfully assert that any PTA reduction for this filing was obviated by the filing of the CPA on December 11, 2000. Thus, no reduction of PTA should be made pursuant to 37 C.F.R. § 1.704(c)(10).
- 20. A CPA was filed on December 11, 2000, as discussed in detail above. Thus, pursuant to 37 C.F.R. § 1.704(c)(11), no periods of adjustment prior to December 11, 2000 have been addressed herein.

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21. Other than the circumstances described above, there have been no circumstances that could reasonably be construed as a failure to engage in reasonable efforts to conclude processing or examination of this application.

### **CONCLUSION**

Applicants respectfully request that the PTA for the instant application be reconsidered in light of the facts and circumstances described above. In particular, Applicants maintain that the instant application is entitled to at least 388 days of PTA.

If any further information is required, please contact the undersigned at the number listed below. Please charge any additional fees due in connection with the filing of this paper, or credit any overpayment, to Deposit Account No. 08-3425.

Dated: July 29, 2004

Respectfully submitted,

Mark J. Hyman

Registration No.: 46,789

HUMAN GENOME SCIENCES, INC.

Intellectual Property Dept. 14200 Shady Grove Road Rockville, Maryland 20850 (240) 314-1224



### HUMAN GENOME SCIENCES, IN

Please date stamp and return to addressee on reverse side

Application of: Choi et al.

Application Number: 08/961,083

Filed: October 30, 1997

Title: Streptococcus pneumoniae Antigens

And Vaccines

Group Art Unit: 1641 Examiner: Hines, J.

Attny. Docket No.: PB340P2

## Documents Filed Via Hand Delivery on April 27

1. Postcard (1)

2. Amendment Under 37 C.F.R. § 1.312

3. Fee Transmittal Sheet, with appropriate fee (in dup1.)

4. Statement under 37 C.F.R. §§ 1.821-1.825

5. Substitute Sequence Listing in paper and computer readable form (6 pages)

6. Issue Fee Transmittal, with appropriate fee (in dupl.)

MSM/CB/mpb

Attn.: Legal Dept.



### TES PATENT AND TRADEMARK OFFICE

Application of: Choi et al.

Application Number: 08/961,083

Group Art Unit: 1641

Filed: October 30, 1997

Examiner: Hines, J.

Title: Streptococcus pneumoniae Antigens

And Vaccines

Attny. Docket No.: PB340P2

### AMENDMENT UNDER 37 C.F.R. § 1.312

**BOX: AF** 

**Assistant Commissioner for Patents** 

Washington, D.C. 20231

Sir:

In response to the Notice of Allowance dated 01 February 2000 and in accordance with Rule 312 of the Rules of Practice, please consider the following amendments and remarks. Applicants submit concurrently herewith: (a) a Substitute Sequence Listing in paper and computer readable form; (b) a Statement under 37 C.F.R. §§ 1.821-1.825; (c) an Issue Fee Transmittal, with appropriate fee; and (d) a Fee Transmittal Sheet, with appropriate fee.

### Amendments

### In the title

Please delete the current title and replace therefor -- Streptococcus pneumoniae SP036 polynucleotides, polypeptides, antigens and vaccines --.

### In the specification

Please amend the specification as follows:

Page 1, after the title, please insert -- This application claims benefit of 35 U.S.C. section 119(e) based on copending U.S. Provisional Application Serial No. 60/029,960, filed October 31, 1996--

Page 3, lines 17-18, please delete "sequences shown as SEQ ID NO:2, SEQ ID NO:4, SEQ ID NO:6, and so on through SEQ ID NO:226" and replace therefor -- sequence shown as SEQ ID NO:2 --.

Line 21, please delete "any of the amino acid sequences of the polypeptides" and replace therefor -- the amino acid sequence of the polypeptide --.

Lines 22-23, please delete "any of the amino acid sequences of the polypeptides" and replace therefor -- the amino acid sequence of the polypeptide--.

Page 4, line 5, please delete "any of the polypeptides" and replace therefor -- the polypeptide--.

Page 5, line 10, please delete "one or more of the polynucleotides or polypeptides" and replace therefor -- the polynucleotide and polypeptide--.

Line 22, please delete "amino acid sequences" and replace therefor --the amino acid sequence--.

Line 23-24, please delete "amino acid sequences" and replace therefor --the amino acid sequence--.

Lines 28-29, please delete ", SEQ ID NO:3, SEQ ID NO:5, and so on through SEQ ID NO:225) which are" and replace therefor -- ) which is --.

Page 7, line 16, please delete "of one or more of the *S. pneumoniae* polypeptides" and replace therefor -- the S. *pneumoniae* polypeptide--.

Line 26, please delete "113 open reading frames (ORFs)" and replace therefor -- one open reading frame (ORF)--.

Line 31, please delete "polypeptides" and replace therefor --polypeptide--.

Line 32, please delete "each" and replace therefor --the--.

Line 34, please delete "each" and replace therefor --the--.

Line 36, please delete "SP126" and replace therefor -- SP036--.

Line 37, please delete "126" and replace therefor --036--.

Line 38, please delete "SP126" and replace therefor -- SP036--.

Page 8, line 1, please delete "SEQ ID NO:223" and replace therefor -SEQ ID NO:1--.

Line 2, please delete "SEQ ID NO:224" and replace therefor --SEQ ID NO:2--.

Lines 8-9, please delete "each of the S. pneumoniae polypeptides" and replace therefor -- the S. pneumoniae polypeptide--.

Line 9, please delete "Each" and replace therefor -- The--.

Line 16, please delete "Lys-1 to Ile-10" of SP001, represents a peptide comprising the lysine at position 1 in SEQ ID NO:2 through and including the isoleucine at position 10 in SEQ ID NO:2, but may include more or fewer residuce than those 10" and replace therefor -- "Arg-10 to Arg-17" of SP036, represents a peptide comprising the arginine at position 1 in SEQ ID NO:2 through and including the arginine at position 17 in SEQ ID NO:2, but may include more or fewer residues than those 8.--

Line 24, please delete "each" and replace therefor --the--.

Line 37, please delete "many of the ORFs disclosed herein were" and replace therefor -- the ORF disclosed herein was--.

Page 11, line 8, please delete "a number of the disclosed ORFs" and replace therefor -- the disclosed ORF--.

Lines 14-16, please delete "polypeptides having the amino acid sequences described in Table 1 and shown as SEQ ID NO:2, SEQ ID NO:4, SEQ ID NO:6, and so on through SEQ ID NO:226, which were" and replace therefor --polypeptide having the amino acid sequence described in Table 1 and shown as SEQ ID NO:2, which was--.

Page 12, lines 30-33, please delete ",SEQ ID NO:3, SEQ ID NO:5, and so on through SEQ ID NO:225; DNA molecules comprising the coding sequences for the polypeptides described in Table 1 and shown as SEQ ID NO:2, SEQ ID NO:4, SEQ ID NO:6, and so on through SEQ ID NO:226;" and replace therefor --;DNA molecules comprising the coding sequences for the polypeptide described in Table 1 and shown as SEQ ID NO:2;--.

Page 13, line 2, please delete "any one of those" and replace therefor --that--.

Line 13, please delete "most, if not all, of a" and replace therefor --the--.

Line 17, please delete "nucleotide sequences identified in Table 1 are provided as

SEQ ID NO:1, SEQ ID NO:3, SEQ ID NO:5, and so on through SEQ ID NO:225," and replace therefor --nucleotide sequence identified in Table 1 is provided as SEQ ID NO:1,--.

Line 23, please delete "polyeptides" and replace therefor -polypeptide--.

Line 26, please delete "each" and replace therefor -the--.

Line 28, please delete "polypeptides" and replace therefor -polypeptide--.

Page 14, line 11, please delete "most, if not all, of".

Line 14, please delete "sequences" and replace therefor -- sequence--.

Line 24, please delete "SEQ ID NO:3, SEQ ID NO:5, and so on through SEQ ID NO:225,"

Page 15, line 1, please delete "residues" and replace therefor --residue--.

Line 16, please delete "residues" and replace therefor --residue--.

Lines 30-31, please delete "(e.g., another sequence selected from Table 1)".

Line 34, please delete "polypeptides" and replace therefor --polypeptide--.

Page 16, line 11, please delete "substitution" and replace therefor -- substitutions--.

Line 17, please delete "any of the amino acid sequences of the polypeptides" and replace therefor -- the amino acid sequence of the polypeptide --.

Line 19, please delete "any of the nucleotide sequences" and replace therefor -- the nucleotide sequence--.

Line 36, please delete "some of the nucleic acid sequences" and replace therefor --the nucleic acid sequence--.

Page 17, line 23, please delete "sequences" and replace therefor -- sequence--.

Line 34, please delete "these nucleotide sequences" and replace therefor -- the nucleotide sequence--.

Page 21, lines 24-25, please delete "sequences described in Table 1, and shown as SEQ ID NO:2, SEQ ID NO:4, SEQ ID NO:6, and so on through SEQ ID NO:226" and replace therefor --sequence described in Table 1, and shown as SEQ ID NO:2--.

Line 34, please delete "polypeptides" and replace therefor --polypeptide--.

Page 22, line 3, please delete "epitopes for each polypeptide is delineated" and replace therefor --epitopes for the polypeptide are delineated--.

Line 10, please delete "polypeptides" and replace therefor --polypeptide--.

Line 14, please delete "polypeptides" and replace therefor --polypeptide--.

Line 15, please delete "any one of the polypeptides" and replace therefor -- the polypeptide--.

Page 23, line 7, please delete "sequences shown in Table 1 may have on" and replace therefor --sequence shown in Table 1 may have one--.

Page 25, line 15, please delete "sequences" and replace therefor --sequence--.

Line 20, please delete "polypeptides" and replace therefor --polypeptide--.

Page 29, line 18, please delete "sequences" and replace therefor -- sequence--.

Page 32, line 4, please delete "polypeptides" and replace therefor --polypeptide--.

Page 36, line 26, please delete "more than one of the S. pneumoniae polypeptides" and replace therefor -- the S. pneumoniae polypeptide--.

Line 27, please delete "one or more, for example 2 to 10, of the S. pneumoniae polypeptides" and replace therefor -- the S. pneumoniae polypeptide--.

Line 35, please delete "ofS." and replace therefor -- of S. --.

Line 35, please delete "that" and replace therefor --the--.

Page 37, line 1, please delete "one or more the S. pneumoniae polypeptides" and replace therefor -- the S. pneumoniae polypeptide--.

Line 2, please delete "the S. pneumoniae polypeptides" and replace therefor --the S. pneumoniae polypeptide--.

Page 41, line 32, please delete "sequences" and replace therefor -- sequence--.

Line 41, please delete "polypeptides" and replace therefor --polypeptide--.

Line 37, please delete "polypeptides" and replace therefor --polypeptide--.

Page 42, line 8, please delete "polypeptides" and replace therefor -polypeptide--.

Line 15, please delete "NO:227 through SEQ ID NO:452" and replace therefor -- NO:3 thorugh SEQ ID NO:4--

Line 20, please delete "sequences" and replace therefor -- sequence--.

Page 43, line 4, please delete "4 C" and replace therefor --4°C--.

Line 24, please delete "sequences" and replace therefor -- sequence--.

Line 28, please delete "Each of the polynucleotides" and replace therefor -- The polynucleotide--.

Lines 30-34, please delete "These pQE10 plasmids containing the DNAs of Table 1, except SP023, SP042, SP054, SP063, SP081, SP092, SP114, SP122, SP123, SP126, and SP127, were deposited with the ATCC as a pooled deposit as a convenience to those of skill in the art. This pooled deposit was desposited on October 16, 1997 and given ATCC Deposit No. 209369. Those of ordinary skill in the art appreciate that isolating an individual plasmid from the pooled deposit is trivial provided the information and reagents described herein. Each of the deposited clones is capable of expressing its encoded *S. pneumoniae* polypeptide."

Page 47, line 18, after "incorporated by reference" please insert --; however, U.S. Provisional Application Serial No. 60/029,960, filed October 31, 1996, is not incorporated by reference.--

Please delete Table 1, Table 2 and Table 3 at pages 48-110 and replace therefor with the following new Tables 1, 2 and 3:

### Table 1

### SP036 nucleotide (SEQ ID NO:1)

TTCTTACGAGTTGGGACTGTATCAAGCTAGAACGGTTAAGGAAAATAATCGTGTTTCCTATATAGATGGAAAACA AGCGACGCAAAAAACGGAGAATTTGACTCCTGATGAGGTTAGCAAGCGTGAAGGAATCAATGCTGAGCAAATCGT CATCAAGATAACAGACCAAGGCTATGTCACTTCACATGGCGACCACTATCATTATTACAATGGTAAGGTTCCTTA TGACGCTATCATCAGTGAAGAATTACTCATGAAAGATCCAAACTATAAGCTAAAAGATGAGGATATTGTTAATGA GGTCAAGGGTGGATATGTTATCAAGGTAGATGGAAAATACTATGTTTACCTTAAGGATGCTGCCCACGCGGATAA CGTCCGTACAAAAGAGGAAATCAATCGACAAAAACAAGAGCATAGTCAACATCGTGAAGGTGGAACTCCAAGAAA CGATGGTGCTGTTGCCTTGGCACGTTCGCAAGGACGCTATACTACAGATGATGGTTATATCTTTAATGCTTCTGA TATCATAGAGGATACTGGTGATGCTTATATCGTTCCTCATGGAGATCATTACCATTACATTCCTAAGAATGAGTT ATCAGCTAGCGAGTTGGCTGCAGAAGCCTTCCTATCTGGTCGAGGAAATCTGTCAAATTCAAGAACCTATCG CCGACAAAATAGCGATAACACTTCAAGAACAAACTGGGTACCTTCTGTAAGCAATCCAGGAACTACAAATACTAA CACAAGCAACAACACCAACACTAACAGTCAAGCAAGTCAAAGTAATGACATTGATAGTCTCTTGAAACAGCTCTA CAAACTGCCTTTGAGTCAACGACATGTAGAATCTGATGGCCTTGTCTTTGATCCAGCACAAATCACAAGTCGAAC AGCTAGAGGTGTTGCAGTGCCACACGGAGATCATTACCACTTCATCCCTTACTCTCAAATGTCTGAATTGGAAGA ACGAATCGCTCGTATTATTCCCCTTCGTTATCGTTCAAACCATTGGGTACCAGATTCAAGGCCAGAACAACCAAG TCCACAACCGACTCCGGAACCTAGTCCAGGCCCGCAACCTGCACCAAATCTTAAAATAGACTCAAATTCTTCTTT GGTTAGTCAGCTGGTACGAAAAGTTGGGGAAGGATATGTATTCGAAGAAAAGGGCATCTCTCGTTATGTCTTTGC GAAAGATTTACCATCTGAAACTGTTAAAAATCTTGAAAGCAAGTTATCAAAACAAGAGAGTGTTTCACACACTTT AACTGCTAAAAAAGAAATGTTGCTCCTCGTGACCAAGAATTTTATGATAAAGCATATAATCTGTTAACTGAGGC TCATAAAGCCTTGTTTGNAAATAAGGGTCGTAATTCTGATTTCCAAGCCTTAGACAAATTATTAGAACGCTTGAA TGATGAATCGACTAATAAAGAAAAATTGGTAGATGATTTATTGGCATTCCTAGCACCAATTACCCATCCAGAGCG ACTTGGCAAACCAAATTCTCAAATTGAGTATACTGAAGACGAAGTTCGTATTGCTCAATTAGCTGATAAGTATAC AACGTCAGATGGTTACATTTTTGATGAACATGATATAATCAGTGATGAAGGAGATGCATATGTAACGCCTCATAT GGGCCATAGTCACTGGATTGGAAAAGATAGCCTTTCTGATAAGGAAAAAGTTGCAGCTCAAGCCTATACTAAAGA AAAAGGTATCCTACCTCCATCTCCAGACGCAGATGTTAAAGCAAATCCAACTGGAGATAGTGCAGCAGCTATTTA CAATCGTGTGAAAGGGGAAAAACGAATTCCACTCGTTCGACTTCCATATATGGTTGAGCATACAGTTGAGGTTAA AAACGGTAATTTGATTATTCCTCATAAGGATCATTACCATAATATTAAATTTGCTTGGTTTGATGATCACACATA CAAAGCTCCAAATGGCTATACCTTGGAAGATTTGTTTGCGACGATTAAGTACTACGTAGAACACCCTGACGAACG TCCACATTCTAATGATGGATGGGGCAATGCCAGTGAGCATGTGTTAGGCAAGAAGACCACAGTGAAGATCCAAA TAAGAACTTCAAAGCGGATGAAGAGCCAGTAGAGGAAACACCTGCTGAGCCAGAAGTCCCTCAAGTAGAGACTGA AACAGAAACTCTAGCTGGTTTACGAAATAATTTGACTCTTCAAATTATGGATAACAATAGTATCATGGCAGAAGC 

### SP036 amino acid (SEQ ID NO:2)

SYELGLYQARTVKENNRVSYIDGKQATQKTENLTPDEVSKREGINAEQIVIKITDQGYVTSHGDHYHYYNGKVPY
DAIISEELLMKDPNYKLKDEDIVNEVKGGYVIKVDGKYYVYLKDAAHADNVRTKEEINRQKQEHSQHREGGTPRN
DGAVALARSQGRYTTDDGYIFNASDIIEDTGDAYIVPHGDHYHYIPKNELSASELAAAEAFLSGRGNLSNSRTYR
RQNSDNTSRTNWVPSVSNPGTTNTNTSNNSNTNSQASQSNDIDSLLKQLYKLPLSQRHVESDGLVFDPAQITSRT
ARGVAVPHGDHYHFIPYSQMSELEERIARIIPLRYRSNHWVPDSRPEQPSPQPTPEPSPGPQPAPNLKIDSNSSL
VSQLVRKVGEGYVFEEKGISRYVFAKDLPSETVKNLESKLSKQESVSHTLTAKKENVAPRDQEFYDKAYNLLTEA
HKALFXNKGRNSDFQALDKLLERLNDESTNKEKLVDDLLAFLAPITHPERLGKPNSQIEYTEDEVRIAQLADKYT
TSDGYIFDEHDIISDEGDAYVTPHMGHSHWIGKDSLSDKEKVAAQAYTKEKGILPPSPDADVKANPTGDSAAAIY
NRVKGEKRIPLVRLPYMVEHTVEVKNGNLIIPHKDHYHNIKFAWFDDHTYKAPNGYTLEDLFATIKYYVEHPDER
PHSNDGWGNASEHVLGKKDHSEDPNKNFKADEEPVEETPAEPEVPQVETEKVEAQLKEAEVLLAKVTDSSLKANA
TETLAGLRNNLTLQIMDNNSIMAEAEKLLALLKGSNPSSVSKEKIN

# Table 2 S. pneumoniae Antigenic Epitopes

#### SP036

Arg-10 to Arg-17; Lys-29 to Ser-39; Ser-140 to Ala-153; Arg-158 to Tyr-169; Asp-175 to Ala-183; Gly-216 to Asn-236; Ala-261 to Leu-270; Arg-282 to Phe-291; and Thr-297 to Ala-305; Pro-342 to Gln-362; Phe-455 to Asp-463; His-497 to Thr-511; Ala-521 to Gly-529; Ile-537 to Val-546; Ile-556 to Ala-568; Pro-581 to Ser-595; Glu-670 to Ala-685; Ser-696 to Ala-705 and Leu-782 to Ser-791

### Table 3

| S. pneumoniae ORF Cloning Primers        |          |
|--|----------|
| Sequence                                 | RE       |
| AGTCGGATCCTTCTTACGAGTTGGGACTGTATCAAGC    | Bam HI   |
| AGTCAAGCTTGTTTATTTTTTCCTTACTTACAGATGAAGG | Hind III |
|  | -        |

Please replace the pages of the Sequence Listing at pages 111-388 of the specification with the Substitute Sequence Listing (6 pages, numbered 1-6) submitted herewith.

Please renumber the pages accordingly.

### In the claims:

Please amend the claims as follows:

- -- 198. (Amended) An isolated nucleic acid molecule comprising a polynucleotide selected from the group consisting of:
  - (a) a polynucleotide encoding amino acids 1 to 796 of SEQ ID NO:[56]2;
  - (b) a polynucleotide encoding amino acids 2 to 796 of SEQ ID NO: [56]2;
- (c) a polynucleotide encoding an epitope-bearing portion of amino acid residues 1 to 796 of SEQ ID NO: [56]2;
- (d) a polynucleotide probe encoding at least 15 contiguous amino acid residues of amino acid residues 1 to 796 of SEQ ID NO: [56]2;
- (e) a polynucleotide consisting of at least 50 contiguous nucleotides of nucleotides 1-2389 of SEQ ID NO: [55]1; and

- (f) a polynucleotide completely complementary to a polynucleotide in (a), (b), (c), (d), or (e) above.
- 205. (Amended) The isolated nucleic acid molecule of claim 199, wherein said polynucleotide is SEQ ID NO: [55]1.
- 206. (Amended) The isolated nucleic acid molecule of claim 201, wherein said epitopebearing portion comprises amino residues Arg-10 to Arg-17 of SEQ ID NO: [56]2.
- 207. (Amended) The isolated nucleic acid molecule of claim 201, wherein said epitope-bearing portion comprises amino residues Lys-29 to Ser-39 of SEQ ID NO: [56]2.
- 208. (Amended) The isolated nucleic acid molecule of claim 201, wherein said epitope-bearing portion comprises amino residues Ser-140 to Ala-153 of SEQ ID NO: [56]2.
- 209. (Amended) The isolated nucleic acid molecule of claim 201, wherein said epitopebearing portion comprises amino residues Arg-158 to Tyr-169 of SEQ ID NO: [56]2.
- 210. (Amended) The isolated nucleic acid molecule of claim 201, wherein said epitope-bearing portion comprises amino residues Asp-175 to Ala-183 of SEQ ID NO: [56]2.
- 211. (Amended) The isolated nucleic acid molecule of claim 201, wherein said epitopebearing portion comprises amino residues Gly-216 to Asn-236 of SEQ ID NO: [56]2.
- 212. (Amended) The isolated nucleic acid molecule of claim 201, wherein said epitopebearing portion comprises amino residues Ala-261 to Leu-270 of SEQ ID NO: [56]2.
- 213. (Amended) The isolated nucleic acid molecule of claim 201, wherein said epitope-bearing portion comprises amino residues Arg-282 to Phe-291 of SEQ ID NO: [56]2.
- 214. (Amended) The isolated nucleic acid molecule of claim 201, wherein said epitopebearing portion comprises amino residues Thr-297 to Ala-305 of SEQ ID NO: [56]2.

- 215. (Amended) The isolated nucleic acid molecule of claim 201, wherein said epitope-bearing portion comprises amino residues Pro-342 to Gln-362 of SEQ ID NO: [56]2.
- 216. (Amended) The isolated nucleic acid molecule of claim 201, wherein said epitopebearing portion comprises amino residues Phe-455 to Asp-463 of SEQ ID NO: [56]2.
- 217. (Amended) The isolated nucleic acid molecule of claim 201, wherein said epitopebearing portion comprises amino residues His-497 to Thr-511 of SEQ ID NO: [56]2.
- 218. (Amended) The isolated nucleic acid molecule of claim 201, wherein said epitopebearing portion comprises amino residues Ala-521 to Gly-529 of SEQ ID NO: [56]2.
- 219. (Amended) The isolated nucleic acid molecule of claim 201, wherein said epitopebearing portion comprises amino residues Ile-537 to Val-546 of SEQ ID NO: [56]2.
- 220. (Amended) The isolated nucleic acid molecule of claim 201, wherein said epitope-bearing portion comprises amino residues Ile-556 to Ala-568 of SEQ ID NO: [56]2.
- 221. (Amended) The isolated nucleic acid molecule of claim 201, wherein said epitopebearing portion comprises amino residues Pro-581 to Ser-595 of SEQ ID NO: [56]2.
- 222. (Amended) The isolated nucleic acid molecule of claim 201, wherein said epitopebearing portion comprises amino residues Glu-670 to Ala-685 of SEQ ID NO: [56]2.
- 223. (Amended) The isolated nucleic acid molecule of claim 201, wherein said epitope-bearing portion comprises amino residues Ser-696 to Ala-705 of SEQ ID NO: [56]2.
- 224. (Amended) The isolated nucleic acid molecule of claim 201, wherein said epitope-bearing portion comprises amino residues Leu-782 to Ser-791 of SEQ ID NO: [56]2.

- 225. (Amended) The isolated nucleic acid molecule of claim 202, wherein said polynucleotide encodes at least 30 contiguous amino acid residues of amino acid residues 1 to 796 of SEQ ID NO: [56]2.
- 226. (Amended) The isolated nucleic acid molecule of claim 203, wherein said polynucleotide consists of at least 100 contiguous nucleotides of nucleotides 1-2389 of SEQ ID NO: [55]1.
- 237. (Amended) An isolated polypeptide comprising a member selected from the group consisting of:
  - (a) a polypeptide of amino acid residues 1 to 796 of SEQ ID NO: [56]2;
  - (b) a polypeptide of amino acid residues 2 to 796 of SEQ ID NO: [56]2; and
- (c) an epitope-bearing portion of a polypeptide consisting of amino acid residues 1 to 796 of SEQ ID NO: [56]2.
- 241. (Amended) The isolated polypeptide of claim 240, wherein said epitope-bearing portion comprises amino residues Arg-10 to Arg-17 of SEQ ID NO: [56]2.
- 242. (Amended) The isolated polypeptide of claim 240, wherein said epitope-bearing portion comprises amino residues Lys-29 to Ser-39 of SEQ ID NO: [56]2.
- 243. (Amended) The isolated polypeptide of claim 240, wherein said epitope-bearing portion comprises amino residues Ser-140 to Ala-153 of SEQ ID NO: [56]2.
- 244. (Amended) The isolated polypeptide of claim 240, wherein said epitope-bearing portion comprises amino residues Arg-158 to Tyr-169 of SEQ ID NO. [56]2.
- 245. (Amended) The isolated polypeptide of claim 240, wherein said epitope-bearing portion comprises amino residues Asp-175 to Ala-183 of SEQ ID NO: [56]2.
- 246. (Amended) The isolated polypeptide of claim 240, wherein said epitope-bearing portion comprises amino residues Gly-216 to Asn-236 of SEQ ID NO: [56]2.

- 247. (Amended) The isolated polypeptide of claim 240, wherein said epitope-bearing portion comprises amino residues Ala-261 to Leu-270 of SEQ ID NO: [56]2.
- 248. (Amended) The isolated polypeptide of claim 240, wherein said epitope-bearing portion comprises amino residues Arg-282 to Phe-291 of SEQ ID NO: [56]2.
- 249. (Amended) The isolated polypeptide of claim 240, wherein said epitope-bearing portion comprises amino residues Thr-297 to Ala-305 of SEQ ID NO: [56]2.
- 250. (Amended) The isolated polypeptide of claim 240, wherein said epitope-bearing portion comprises amino residues Pro-342 to Gln-362 of SEQ ID NO: [56]2.
- 251. (Amended) The isolated polypeptide of claim 240, wherein said epitope-bearing portion comprises amino residues Phe-455 to Asp-463 of SEQ ID NO: [56]2.
- 252. (Amended) The isolated polypeptide of claim 240, wherein said epitope-bearing portion comprises amino residues His-497 to Thr-511 of SEQ ID NO: [56]2.
- 253. (Amended) The isolated polypeptide of claim 240, wherein said epitope-bearing portion comprises amino residues Ala-521 to Gly-529 of SEQ ID NO: [56]2.
- 254. (Amended) The isolated polypeptide of claim 240, wherein said epitope-bearing portion comprises amino residues Ile-537 to Val-546 of SEQ ID NO: [56]2.
- 255. (Amended) The isolated polypeptide of claim 240, wherein said epitope-bearing portion comprises amino residues Ile-556 to Ala-568 of SEQ ID NO: [56]2.
- 256. (Amended) The isolated polypeptide of claim 240, wherein said epitope-bearing portion comprises amino residues Pro-581 to Ser-595 of SEQ ID NO: [56]2.

- 257. (Amended) The isolated polypeptide of claim 240, wherein said epitope-bearing portion comprises amino residues Glu-670 to Ala-685 of SEQ ID NO: [56]2.
- 258. (Amended) The isolated polypeptide of claim 240, wherein said epitope-bearing portion comprises amino residues Ser-696 to Ala-705 of SEQ ID NO: [56]2.
- 259. (Amended) The isolated polypeptide of claim 240, wherein said epitope-bearing portion comprises amino residues Leu-782 to Ser-791 of SEQ ID NO: [56]2.
- 265. (Amended) The method of claim 17 wherein the polypeptide comprises amino acid residues 1 to 796 of SEQ ID NO:[56]2.
- 267. (Amended) The method of claim 17 wherein the polypeptide comprises an epitope-bearing portion of amino acid residues 1 to 796 of SEQ ID NO:[56]2.

### Remarks

Claims 17-18 and 198-268 are allowed.

The title has been amended to more particularly identify the claimed invention.

The specification has been amended to: (a) delete text in the specification relating to the non-elected species and to cancel all sequence listings relating to the non-elected species; (b) recite sequence identifiers associated with the elected polynucleotides and polypeptides throughout the specification and the claims; (c) incorporate the Substitute Sequence Listing pursuant to 37 C.F.R. § 1.821 (c) and (d) renumber the pages of the claims accordingly. The above-mentioned amendments do not constitute new matter under 35 U.S.C. § 112.

Applicants submit that entry of the instant amendment does not raise new issues.

Particularly, as disclosed in the specification, Applicant's invention is considered to be the sequence corresponding to an individual polynucleotide or fragment of the Streptococcus Pneumoniae genome (see, e.g., page 6, lines 16-19), as each polynucleotide fragment or ORF of the genome is separately patentable in its own right. This position is bolstered by the Patent Office's arguments in the record that the non-elected sequences are not related to the claimed invention, as demonstrated by the fact that the Patent Office has restricted and

withdrawn claims directed to non-elected sequences throughout the prosecution of the instant application.

Deletion of the reference to ATCC Deposit No. 209369 does not raise a new issue because the polynucleotide and polypeptide sequences disclosed in Table 1, as SEQ ID Nos: 1 and 2, were also available in the library deposited as ATCC Deposit No. 97755, or from DNA isolated from the same organism, such as the S. pneumoniae strain deposited with the ATCC as Deposit No. 55840. Both ATCC Deposit No. 97755 and ATCC Deposit No. 55840 are discussed in the instant specification at page 42, lines 1 to 4.

The sequences of the non-elected species are not required to support the elected claims under 35 U.S.C. §§ 101 and 112. Applicants point out that, as disclosed in the specification, a polynucleotide sequence corresponding to a single Streptococcus pneumoniae ORF can be used, for example, as a diagnostic probe to detect Streptococcus pneumoniae in a sample (see, e.g., page 46, lines 17-32). Applicants submit that on the priority date of the instant application, the skilled molecular biologist, enlightened by the teaching of the amended specification (i.e., the disclosure of the specification pending upon entry of the instant amendment) was more than capable of routinely generating the claimed polynucleotides and using the polynucleotides to express polypeptides, diagnose the presence of polynucleotides that hybridize to the claimed polynucleotides and to use the polypeptides of the invention to attenuate a Streptococcus infection. Further, amending the specification to delete text relating to the non-elected species and to cancel all sequence listings relating to the non-elected species, does not increase the scope of the claimed polynucleotides when compared to that prior to amending the specification. Further, deletion of disclosure relating to the non-claimed sequences does not constitute new matter.

### Conclusion

Applicants respectfully request that the amendments and remarks of the present response be entered and made of record in the present application. Early notice to that effect

<sup>&</sup>lt;sup>1</sup> Applicants additionally point out that the publication and/or release of Applicants' proprietary information concerning the non-elected subject matter is not commensurate with the rights which would ultimately be granted to Applicants for the elected species.

is earnestly solicited. If, in the opinion of the Examiner, a telephone conference would expedite prosecution, the undersigned can be reached at the telephone number indicated below. If a fee is required in connection with this paper, please charge Deposit Account No. 08-3425 for the appropriate amount.

Respectfully submitted,

Date: Mn 27 2000

Michelle S. Marks (Reg. No. 41,971)

Attorney for Applicants

Human Genome Sciences, Inc.

9410 Key West Avenue Rockville, MD 20850 (301) 610-5761 (phone)

MSM/CCB



### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Choi et al.

Application Number: 08/961,083

Group Art Unit: 1641

Filed: October 30, 1997

Examiner: Hines, J.

Title: Streptococcus pneumoniae Antigens

And Vaccines

Attny. Docket No.: PB340P2

### **STATEMENT UNDER 37 C.F.R. 1.821 and 1.825**

**Assistant Commissioner For Patents** Washington, D.C. 20231

Sir:

Applicants hereby certify under 37 C.F.R. §§1.821(f) and 1.825(b) that the paper copy of the Substitute Sequence Listing, and the computer readable form of the Substitute Sequence Listing submitted herewith, are the same.

Moreover, applicants hereby certify under 37 C.F.R. §§1.821(g) and 1.825(a) the Substitute Sequence Listing contains no new matter.

No fee is believed due in connection with this submission. However, should a fee be required, the Assistant Commissioner is hereby authorized to charge such fee to Deposit Account No. 08-3425. A duplicate of this sheet is enclosed.

Respectfully submitted,

(Reg. No. 41,971)

Attorney for Applicants

Human\_Genome\_Sciences,\_Inc.\_

9410 Key West Avenue Rockville, MD 20850 (301) 610-5761 (phone)

MDS/CB/mbp



### SEQUENCE LISTING

### 1) GENERAL INFORMATION:

- (i) APPLICANT: Choi et. al.
- (ii) TITLE OF INVENTION: Streptococcus pneumoniae Antigens and Vaccines
  - (iii) NUMBER OF SEQUENCES: 4
  - (iv) CORRESPONDENCE ADDRESS:
    - (A) ADDRESSEE: Human Genome Sciences, Inc.
    - (B) STREET: 9410 Key West Avenue
    - (C) CITY: Rockville
    - (D) STATE: Maryland
    - (E) COUNTRY: USA
    - (F) ZIP: 20850
  - (v) COMPUTER READABLE FORM:
    - (A) MEDIUM TYPE: Diskette, 3.50 inch, 1.4Mb storage
    - (B) COMPUTER: HP Vectra 486/33
    - (C) OPERATING SYSTEM: MSDOS version 6.2
    - (D) SOFTWARE: ASCII Text
  - (vi) CURRENT APPLICATION DATA:
    - (A) APPLICATION NUMBER: 08/961,083
    - (B) FILING DATE:OCT-30-1997
    - (C) CLASSIFICATION:
  - (vii) PRIOR APPLICATION DATA:
    - (A) APPLICATION NUMBER: 60/029,960
    - (B) FILING DATE:OCT-31-1996
  - (viii) ATTORNEY/AGENT INFORMATION:
    - (A) NAME: Michelle S. Marks
    - (B) REGISTRATION NUMBER: 41,971
    - (C) REFERENCE/DOCKET NUMBER: PB340P2
  - (vi)-TELECOMMUNICATION INFORMATION:
    - (A) TELEPHONE: (301) 309-8504
    - (B) TELEFAX: (301) 309-851-2-
- (2) INFORMATION FOR SEQ ID NO: 1:
  - (i) SEQUENCE CHARACTERISTICS:
    - (A) LENGTH: 2389 base pairs
    - (B) TYPE: nucleic acid
    - (C) STRANDEDNESS: double
    - (D) TOPOLOGY: linear
  - (xi) SEQUENCE DESCRIPTION: SEQ ID NO: 1:

| • | TTCTTACGAG | TTGGGACTGT | ATCAAGCTAG | AACGGTTAAG | GAAAATAATC | GTGTTTCCTA | 60   |
|---|------------|------------|------------|------------|------------|------------|------|
| - | TATAGATGGA | AAACAAGCGA | CGCAAAAAAC | GGAGAATTTG | ACTCCTGATG | AGGTTAGCAA | 120  |
|   | GCGTGAAGGA | ATCAATGCTG | AGCAAATCGT | CATCAAGATA | ACAGACCAAG | GCTATGTCAC | 180  |
|   | TTCACATGGC | GACCACTATC | ATTATTACAA | TGGTAAGGTT | CCTTATGACG | CTATCATCAG | 240  |
|   | TGAAGAATTA | CTCATGAAAG | ATCCAAACTA | TAAGCTAAAA | GATGAGGATA | TTGTTAATGA | 300  |
| • | GGTCAAGGGT | GGATATGTTA | TCAAGGTAGA | TGGAAAATAC | TATGTTTACC | TTAAGGATGC | 360  |
| • | TGCCCACGCG | GATAACGTCC | GTACAAAAGA | GGAAATCAAT | CGACAAAAAC | AAGAGCATAG | 420  |
|   | TCAACATCGT | GAAGGTGGAA | CTCCAAGAAA | CGATGGTGCT | GTTGCCTTGG | CACGTTCGCA | 480  |
|   | AGGACGCTAT | ACTACAGAŢG | ATGGTTATAT | CTTTAATGCT | TCTGATATCA | TAGAGGATAC | 540  |
|   | TGGTGATGCT | TATATCGTTC | CTCATGGAGA | TCATTACCAT | TACATTCCTA | AGAATGAGTT | 600  |
|   | ATCAGCTAGC | GAGTTGGCTG | CTGCAGAAGC | CTTCCTATCT | GGTCGAGGAA | ATCTGTCAAA | 660  |
|   | TTCAAGAACC | TATCGCCGAC | AAAATAGCGA | TAACACTTCA | AGAACAAACT | GGGTACCTTC | 720  |
|   | TGTAAGCAAT | CCAGGAACTA | CAAATACTAA | CACAAGCAAC | AACAGCAACA | CTAACAGTCA | 780  |
|   | AGCAAGTCAA | AGTAATGACA | TTGATAGTCT | CTTGAAACAG | CTCTACAAAC | TGCCTTTGAG | 840  |
|   | TCAACGACAT | GTAGAATCTG | ATGGCCTTGT | CTTTGATCCA | GCACAAATCA | CAAGTCGAAC | 900  |
|   | AGCTAGAGGT | GTTGCAGTGC | CACACGGAGA | TCATTACCAC | TTCATCCCTT | ACTCTCAAAT | 960  |
|   | GTCTGAATTG | GAAGAACGAA | TCGCTCGTAT | TATTCCCCTT | CGTTATCGTT | CAAACCATTG | 1020 |
|   | GGTACCAGAT | TCAAGGCCAG | AACAACCAAG | TCCACAAÇCG | ACTCCGGAAC | CTAGTCCAGG | 1080 |
|   | CCCGCAACCT | GCACCAAATC | TTAAAATAGA | CTCAAATTCT | TCTTTGGTTA | GTCAGCTGGT | 1140 |
|   | ACGAAAAGTT | GGGGAAGGAT | ATGTATTCGA | AGAAAAGGGC | ATCTCTCGTT | ATGTCTTTGC | 1200 |
|   | GAAAGATTTA | CCATCTGAAA | CTGTTAAAAA | TCTTGAAAGC | AAGTTATCAA | AACAAGAGAG | 1260 |
|   | TGTTTCACAC | ACTTTAACTG | CTAAAAAAGA | AAATGTTGCT | CCTCGTGACC | AAGAATTTTA | 1320 |
|   | TGATAAAGCA | TATAATCTGT | TAACTGAGGC | TCATAAAGCC | TTGTTTGNAA | ATAAGGGTCG | 1380 |
|   | TAATTCTGAT | TTCCAAGCCT | TAGACAAATT | ATTAGAACGC | TTGAATGATG | AATCGACTAA | 1440 |
|   | TAAAGAAAAA | TTGGTAGATG | ATTTATTGGC | ATTCCTAGCA | CCAATTACCC | ATCCAGAGCG | 1500 |
|   | ACTTGGCAAA | CCAAATTCTC | AAATTGAGTA | TACTGAAGAC | GAAGTTCGTA | TTGCTCAATT | 1560 |
|   | AGCTGATAAG | TATACAACGT | CAGATGGTTA | CATTTTTGAT | GAACATGATA | TAATCAGTGA | 1620 |
|   | TGAAGGAGAT | GCATATGTAA | CGCCTCATAT | GGGCCATAGT | CACTGGATTG | GAAAAGATAG | 1680 |
|   | CCTTTCTGAT | AAGGAAAAAG | TTGCAGCTCA | AGCCTATACT | AAAGAAAAAG | GTATCCTACC | 1740 |
|   | TCCATCTCCA | GACGCAGATG | TTAAAGCAAA | TCCAACTGGA | GATAGTGCAG | CAGCTATTTA | 1800 |
|   | CAATCGTGTG | AAAGGGGAAA | AACGAATTCC | ACTCGTTCGA | CTTCCATATA | TGGTTGAGCA | 1860 |
|   | TACAGTTGAG | GTTAAAAACG | GTAATTTGAT | TATTCCTCAT | AAGGATCATT | ACCATAATAT | 1920 |
|   |            |            |            |            |            |            |      |

| TAAATTTGCT | TGGTTTGATG | ATCACACATA | CAAAGCTCCA | AATGGCTATA | CCTTGGAAGA | 1980 |
|------------|------------|------------|------------|------------|------------|------|
| TTTGTTTGCG | ACGATTAAGT | ACTACGTAGA | ACACCCTGAC | GAACGTCCAC | ATTCTAATGA | 2040 |
| TGGATGGGGC | AATGCCAGTG | AGCATGTGTT | AGGCAAGAAA | GACCACAGTG | AAGATCCAAA | 2100 |
| TAAGAACTTC | AAAGCGGATG | AAGAGCCAGT | AGAGGAAACA | CCTGCTGAGC | CAGAAGTCCC | 2160 |
| TCAAGTAGAG | ACTGAAAAAG | TAGAAGCCCA | ACTCAAAGAA | GCAGAAGTTT | TGCTTGCGAA | 2220 |
| AGTAACGGAT | TCTAGTCTGA | AAGCCAATGC | AACAGAAACT | CTAGCTGGTT | TACGAAATAA | 2280 |
| TTTGACTCTT | CAAATTATGG | ATAACAATAG | TATCATGGCA | GAAGCAGAAA | AATTACTTGC | 2340 |
| GTTGTTAAAA | GGAAGTAATC | CTTCATCTGT | AAGTAAGGAA | AAAATAAAC  |            | 2389 |

### (2) INFORMATION FOR SEQ ID NO: 2:

- (i) SEQUENCE CHARACTERISTICS:
  - (A) LENGTH: 796 amino acids
  - (B) TYPE: amino acid
  - (C) STRANDEDNESS: single
  - (D) TOPOLOGY: linear
- (ii) MOLECULE TYPE: protein

### (xi) SEQUENCE DESCRIPTION: SEQ ID NO:2:

Ser Tyr Glu Leu Gly Leu Tyr Gln Ala Arg Thr Val Lys Glu Asn Asn 1 5 10 15

Arg Val Ser Tyr Ile Asp Gly Lys Gln Ala Thr Gln Lys Thr Glu Asn 20 25 30

Leu Thr Pro Asp Glu Val Ser Lys Arg Glu Gly Ile Asn Ala Glu Gln
35 40 45

Ile Val Ile Lys Ile Thr Asp Gln Gly Tyr Val Thr Ser His Gly Asp 50 60

His Tyr His Tyr Tyr Asn Gly Lys Val Pro Tyr Asp Ala Ile Ile Ser 65 70 75 80

Glu Glu Leu Leu Met Lys Asp Pro Asn Tyr Lys Leu Lys Asp Glu Asp

Ile-Val-Asn-Glu-Val-Lys-Gly-Gly-Tyr-Val-Ile-Lys-Val-Asp-Gly-Lys
100 105 110

Tyr Tyr Val Tyr Leu Lys Asp Ala Ala His Ala Asp Asn Val Arg Thr 115 120 125

Lys Glu Glu Ile Asn Arg Gln Lys Gln Glu His Ser Gln His Arg Glu 130 135 140

Gly Gly Thr Pro Arg Asn Asp Gly Ala Val Ala Leu Ala Arg Ser Gln 145 150 155 160

Gly Arg Tyr Thr Thr Asp Asp Gly Tyr Ile Phe Asn Ala Ser Asp Ile 165 170 175

|   | 116        | GIU        | Asp        | 180         | сту        | Asp        | Ala        | TYF        | 185        | vai        | PIO        | nis        | GIŸ        | 190        | nis        | TYL                |
|---|------------|------------|------------|-------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|--------------------|
|   | His        | Tyr        | Ile<br>195 | Pro         | Lys        | Asn        | Glu        | Leu<br>200 | Ser        | Ala        | Ser        | Glu        | Leu<br>205 | Ala        | Ala        | Ala                |
|   | Glu        | Ala<br>210 | Phe        | Leu         | Ser        | Gly        | Arg<br>215 | Gly        | Asn        | Leu        | Ser        | Asn<br>220 | Ser        | Arg        | Thr        | Tyr                |
|   | Arg<br>225 | Arg        | Gln        | Asn         | Ser        | Asp<br>230 | Asn        | Thr        | Ser        | Arg        | Thr<br>235 | Asn        | Trp        | Val        | Pro        | Ser<br>240         |
|   | Val        | Ser        | Asn        | Pro         | Gly<br>245 | Thr        | Thr        | Asn        | Thr        | Asn<br>250 | Thr        | Ser        | Asn        | Asn        | Ser<br>255 | Asn                |
|   | Thr        | Asn        | Ser        | Gln<br>260  | Ala        | Ser        | Gln        | Ser        | Asn<br>265 | Asp        | Ile        | Asp        | Ser        | Leu<br>270 | Leu        | Lys                |
|   | Gln        | Leu        | Tyr<br>275 | Lys         | Leu        | Pro        | Leu        | Ser<br>280 | Gln        | Arg        | His        | Val        | Glu<br>285 | Ser        | Asp        | Gly                |
|   | Leu        | Val<br>290 | Phe        | Asp         | Pro        | Ala        | Gln<br>295 | Ile        | Thr        | Ser        | Arg        | Thr<br>300 | Ala        | Arg        | Gly        | Val                |
|   | Ala<br>305 | Val        | Pro        | His         | Gly        | Asp<br>310 | His        | Tyr        | His        | Phe        | Ile<br>315 | Pro        | Tyr        | Ser        | Gln        | Met<br>320         |
|   | Ser        | Glu        | Leu        | Glu         | Glu<br>325 | Arg        | Ile        | Ala        | Arg        | 11e<br>330 | Ile        | Pro        | Leu        | Arg        | Tyr<br>335 | Arg                |
|   | Ser        | Asn        | His        | Trp<br>340  | Val        | Pro        | Asp        | Ser        | Arg<br>345 | Pro        | Glu        | Gln        | Pro        | Ser<br>350 | Pro        | Gln                |
|   | Pro        | Thr        | Pro<br>355 | Glu         | Pro        | Ser        | Pro        | Gly<br>360 | Pro        | Gln        | Pro        | Ala        | Pro<br>365 | Asn        | Leu        | Lys                |
|   | Ile        | Asp<br>370 | Ser        | Asn         | Ser        | Ser        | Leu<br>375 | Val        | Ser        | Gln        | Leu        | Val<br>380 | Arg        | Lys        | Val        | Gly                |
|   | Glu<br>385 | Gly        | Tyr        | Val         | Phe        | Glu<br>390 | Glu        | Lys        | Gly        | Ile        | Ser<br>395 | Arg        | Tyr        | Val        | Phe        | Ala<br>400         |
|   | Lys        | Asp        | Leu        | Pro         | Ser<br>405 | Glu        | Thr        | Val        | Lys        | Asn<br>410 | Leu        | Glu        | Ser        | Lys        | Leu<br>415 | Ser                |
| _ | Lys        | Gln        | Glu        | Ser<br>-420 | Val        | Ser        | His        | Thr        | Leu<br>425 |            | Ala        | Lys        | Lys        | Glu<br>430 |            | Val                |
| _ | Ala        | -Pro-      | Arg<br>435 | -Asp        | Gln        | -Glu       | Phe        | Tyr<br>440 | Asp        | Lys-       | Ala        | -Туг       | Asn<br>445 | Leu        | Leu        | -Th <del>r</del> - |
|   | Glu        | Ala<br>450 | His        | Lys         | Ala        | Leu        | Phe<br>455 | Xaa        | Asn        | Lys        | Gly        | Arg<br>460 | Asn        | Ser        | Asp        | Phe                |
|   | Gln<br>465 | Ala        | Leu        | Asp         | Lys        | Leu<br>470 | Leu        | Glu        | Arg        | Leu        | Asn<br>475 | Asp        | Glu        | Ser        | Thr        | Asn<br>480         |
|   | Lys        | .Glu       | Lys        | Leu         | Val<br>485 | Asp        | Asp        | Leu        | Leu        | Ala<br>490 | Phe        | Leu        | Ala        | Pro        | Ile<br>495 | Thr                |
|   | His        | Pro        | Glu        | Arg<br>500  | Leu        | Gly        | Lys        | Pro        | Asn<br>505 | Ser        | Gln        | Ile        | Glu        | Tyr<br>510 | Thr        | Glu                |

|            |            |            | Lys<br>740<br>Gly |            |            | _          |            | 745        |                   | _          |            |            | 750        |            |            |
|------------|------------|------------|-------------------|------------|------------|------------|------------|------------|-------------------|------------|------------|------------|------------|------------|------------|
| Gln        | Val        | 'Glu       | Thr               | Glu<br>725 | Lys        | Val        | Glu        | Ala        | Gln<br>730        | Leu        | Lys        | Glu        | Ala        | Glu<br>735 | Val        |
| Ala<br>705 | Asp        | Glu        | Glu               | Pro        | Val<br>710 | Glu        | Glu        | Thr        | Pro               | Ala<br>715 | Glu        | Pro        | Glu        | Val        | Pro<br>720 |
| Val        | Leu<br>690 | Gly        | Lys               | Lys        | Asp        | His<br>695 | Ser        | Glu        | Asp               | Pro        | Asn<br>700 | _          | Asn        | Phe        | Lys        |
| Asp        | Glu        | Arg<br>675 | Pro               | His        | Ser        | Asn        | Asp<br>680 | Gly        | Trp               | Gly        | Asn        | Ala<br>685 | Ser        | Glu        | His        |
| Thr        | Leu        | Glu        | Asp<br>660        | Leu        | Phe        | Ala        | Thr        | Ile<br>665 | Lys               | Tyr        | Tyr        | Val        | Glu<br>670 | His        | Pro        |
| Lys        | Phe        | Ala        | Trp               | Phe<br>645 | Asp        | Asp        | His        | Thr        | <b>Tyr</b><br>650 | Lys        | Ala        | Pro        | Asn        | Gly<br>655 | Tyr        |
| Lys<br>625 | Asn        | Gly        | Asn               | Leu        | 11e<br>630 | Ile        | Pro        | His        | Lys               | Asp<br>635 | His        | туг        | His        | Asn        | Ile<br>640 |
| Ile        | Pro<br>610 | Leu        | Val               | Arg        | Leu        | Pro<br>615 | Tyr        | Met        | Val               | Glu        | His<br>620 | Thr        | Val        | Glu        | Val        |
| Gly        | Asp        | Ser<br>595 | Ala               | Ala        | Ala        | Ile        | Tyr<br>600 | Asn        | Arg               | Val        | Lys        | Gly<br>605 | Glu        | Lys        | Arg        |
| Gly        | Ile        | Leu        | Pro<br>580        | Pro        | Ser        | Pro        | Asp        | Ala<br>585 | Asp               | Val        | Lys        | Ala        | Asn<br>590 | Pro        | Thr        |
| Leu        | Ser        | Asp        | Lys               | Glu<br>565 | Lys        | Val        | Ala        | Ala        | Gln<br>570        | Ala        | Tyr        | Thr        | Lys        | Glu<br>575 | Lys        |
| Tyr<br>545 | Val        | Thr        | Pro               | His        | Met<br>550 | Gly        | His        | Ser        | His               | Trp<br>555 | Ile        | Gly        | Lys        | Asp        | Ser<br>560 |
| Gly        | Tyr<br>530 | Ile        | Phe               | Asp        | Glu        | His<br>535 | Asp        | Ile        | Ile               | Ser        | Asp<br>540 | Glu        | Gly        | Asp        | Ala        |
| Asp        | Glu        | Val<br>515 | Arg               | Ile        | Ala        | Gln        | Leu<br>520 | Ala        | Asp               | Lys        | Tyr        | Thr<br>525 | Thr        | Ser        | Asp        |
|            |            |            |                   |            |            |            |            |            |                   |            |            |            |            |            |            |

Asn Ser Ile Met Ala Glu Ala Glu Lys Leu Leu Ala Leu Leu Lys Gly 775 780

Ser Asn Pro Ser Ser Val Ser Lys Glu Lys Ile Asn 785 790 795

### (2) INFORMATION FOR SEQ ID NO: 3:

- (i) SEQUENCE CHARACTERISTICS:
  - (A) LENGTH: 37 base pairs

  - (B) TYPE: nucleic acid (C) STRANDEDNESS: double
  - (D) TOPOLOGY: linear

| (xi) SEQUENCE DESCRIPTION: SEQ ID NO: 3:   |    |
|--|----|
| AGTCGGATCC TTCTTACGAG TTGGGACTGT ATCAAGC   | 37 |
| (2) INFORMATION FOR SEQ ID NO: 4:  |    |
| <ul> <li>(i) SEQUENCE CHARACTERISTICS:</li> <li>(A) LENGTH: 40 base pairs</li> <li>(B) TYPE: nucleic acid</li> <li>(C) STRANDEDNESS: double</li> <li>(D) TOPOLOGY: linear</li> </ul> |    |
| (xi) SEQUENCE DESCRIPTION: SEQ ID NO: 4:   | ·  |
|  | 40 |

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Choi et al.

Application Serial No.: 08/961,083

Art Unit: 1641

Filed: October 30, 1997

Examiner: Hines, J.

For:

Streptococcus Pneumoniae Antigens

and Vaccines

Attorney Docket No.: PB340P2

### **FEE TRANSMITTAL SHEET**

Assistant Commissioner for Patents Washington, D.C. 20231

Sir:

The fee required to be filed with the accompanying amendment of even date herewith concerning the above-identified application has been estimated to be \$0.00.

The claim amendment fee has been estimated as shown below:

|   | (Col. 1)              |              | (Col. 2)    | Col. 3) |                 | IALL<br>TITY |             | OTHER THAN A<br>SMALL ENTITY |              |               |  |
|---|-----------------------|--------------|-------------|---------|-----------------|--------------|-------------|------------------------------|--------------|---------------|--|
| Claims<br>Remaining<br>After<br>Amendment |                       |              | 1           |         | resent<br>Extra | Rate         | Add.<br>Fee | or                           | Rate         | Add. Fee      |  |
| Total                                     | 73                    | Minus        | 181         |         | -               | X9           | \$ **       | •                            | X18          | \$.00         |  |
| Indep                                     | 13                    | Minus        | 13          | =       | -               | X39          | \$ **       |                              | X78          | \$.00         |  |
| F   | First Presentation of | f Multiple I | Dep. Claims |         |                 | + 135        | \$ **       |                              | <b>- 270</b> | \$**          |  |
|   |                       |              |             |         |                 |              | \$ **       | or                           | Total        | <u>\$0.00</u> |  |

Please charge the required fee, and any other fee deemed necessary, to Deposit Account No. 08-3425. A duplicate of this sheet is enclosed.

Respectfully submitted,

Date:

Mickelle'S. Marks

(Reg. No. 41,971)

Attorney for Applicants

Human Genome Sciences, Inc.

9410 Key West Avenue Rockville, MD 20850 (301) 610-5771 (phone)

MSM/mbp

### PART B-ISSUE FEE TRANSMITTAL

complete and mail this form, together with ap

le fees, to:

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Assistant Commissioner for Patent

Washington, D.C. 20231

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Wichelle S. Marks

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### HUMAN GENOME SCIENCES LEGAL DEPARTMENT

9410 Key West Avenue Rockville, MD 20850

Phone: 301-309-8504

Fax: 301-309-8439

# **FAX COVER SHEET**

Date: December 11, 2000

Number of pages, including cover: 23

To:

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Marianne Morgan

Office of the Petitioner

U.S. Patent and Trademark Office

Fax: 703-308-6916

Phone:

From: Kenley K. Hoover

U.S. Patent Application No. 08/961,083

HGS Ref.: PB340P2

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| CONTINUED PROSECUI   | TION APPLICATION (CPA)<br>RANSMITTAL   |   |  |  |  |  |  |  |  |  |  |  |
|--|--|---|--|--|--|--|--|--|--|--|--|--|
| Submit an original, and a duplicate for fee pro-   |  | ble:  |  |  |  |  |  |  |  |  |  |  |
| (Only for Continuation or Divisional application   | ns under 37 CFR 1.53(d)) DUPLIC.   |   |  |  |  |  |  |  |  |  |  |  |
| Address to:  | Attorney Docket No.  | PD2 40D2  |  |  |  |  |  |  |  |  |  |  |
| Assistant Commissioner for Patents   | of prior application   | PB340P2   |  |  |  |  |  |  |  |  |  |  |
| ox CPA   |  |   |  |  |  |  |  |  |  |  |  |  |
| Vashington, DC 20231   |  | Choi et al.   |  |  |  |  |  |  |  |  |  |  |
|  | First Named Inventor   | Hines, J.   |  |  |  |  |  |  |  |  |  |  |
|  | Examiner Name  | 1641  |  |  |  |  |  |  |  |  |  |  |
|  | Group/Art Unit   | 1041  |  |  |  |  |  |  |  |  |  |  |
|  | Express Mail Label No.   | (1)   |  |  |  |  |  |  |  |  |  |  |
| his is a request for a Continuation or divisional  |  | (d),  |  |  |  |  |  |  |  |  |  |  |
| continued prosecution application (CPA)) of the prior app  | olication number08/961,083   |   |  |  |  |  |  |  |  |  |  |  |
| led on 10/30/97 entitled: Streptococcus  | s pneumoniae Antigens and Vacc   | ines  |  |  |  |  |  |  |  |  |  |  |
| 100 Oil  |  |   |  |  |  |  |  |  |  |  |  |  |
|  | NOTES  |   |  |  |  |  |  |  |  |  |  |  |
|  | 110120   | 1 1   |  |  |  |  |  |  |  |  |  |  |
| FILING QUALIFICATIONS: The prior application identified above must § 1.51(b) or (2) the national stage of an international application in computitity or a plant application if the prior nonprovisional application was for the filing date of the prior application. See "Request for Continued Exc 65 Fed. Reg. 50092 (Aug 16, 2000); Interim Rule, 65 Fed. Reg. 50092 (Aug 16, 2000); In | priance with 33 0.3.C. 371.2. Jective May 29, 2000. A CPA may be filed in interest of the committee of the c | in a design application regardless<br>Application Practice," Final Rule,<br>Office (Apr. 11, 2000). |  |  |  |  |  |  |  |  |  |  |
| C-I-P NOT PERMITTED: A continuation-in-part application cannot be filed as a CPA under 37 CFR § 1.53(d), but must be filed under 37 CFR § 1.53(b).   |  |   |  |  |  |  |  |  |  |  |  |  |
| EXPRESS ABANDONMENT OF PRIOR APPLICATION: The filing of this CPA is a request to expressly abandon the prior application as of the filing date of the request for a CPA. 37 CFR § 1.53(b) must be used to file a continuation, divisional, or continuation-in-part of an application that is not to be abandoned.  |  |   |  |  |  |  |  |  |  |  |  |  |
| ACCESS TO PRIOR APPLICATION: The filing of this CPA will be construed to include a waiver of confidentiality by the application under 35 U.S.C. 122 to the extent that any member of the public who is entitled under the provisions of 37 CFR § 1.14 to access to, copies of, or information concerning, the prior application may be given similar access to, copies of, or similar information concerning, the other application or applications in the file jacket.  |  |   |  |  |  |  |  |  |  |  |  |  |
| 35 U.S.C. 120 STATEMENT: In a CPA, no reference to the prior app<br>submitted. If a sentence referencing the prior application is submitted, in<br>U.S.C. 120 and to every application assigned the app  | i will not be entered. A request for a CLA is in   | specific rejerence require  |  |  |  |  |  |  |  |  |  |  |
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| Enter the unentered amendment previously filed in the prior nonprovisional application.  | on <u>April 27, 2000</u> under 37  | CFR § 1.312   |  |  |  |  |  |  |  |  |  |  |
| A preliminary amendment is enclosed.   |  |   |  |  |  |  |  |  |  |  |  |  |
| 3. This application is filed by fewer than all the inv   | rentors named in the prior applica   | tion, 37 CFR § 1.53(d)(4).  |  |  |  |  |  |  |  |  |  |  |
| a. DELETE the following inventor(s) name   |  | oplication:   |  |  |  |  |  |  |  |  |  |  |
|  |  |   |  |  |  |  |  |  |  |  |  |  |
| b. The inventor(s) to be deleted are set for   | rth in a separate sheet attached he  | ereto.  |  |  |  |  |  |  |  |  |  |  |
| 4. A new power of attorney or authorization of ago   | ent-(PTO/SB/81)-is-enclosed.   |   |  |  |  |  |  |  |  |  |  |  |
| 5. Information Disclosure Statement (IDS) is enclosed. Information Disclosure Statement (IDS) is enclosed.   | osed:  |   |  |  |  |  |  |  |  |  |  |  |
| b. Copies of IDS citations   |  |   |  |  |  |  |  |  |  |  |  |  |
|  | Page 1 of 21   |   |  |  |  |  |  |  |  |  |  |  |

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| CLAIMS   | (1) FOR                    |  | (2                 | ) NUMBER FILED                    | (3) NUM  | BER EXTRA | (4) RATE                    |              | (5) CALCULATIONS         |  |  |  |
|--|----------------------------|--|--------------------|-----------------------------------|----------|-----------|-----------------------------|--------------|--------------------------|--|--|--|
| 4  | TOTAL CLA<br>(37 CFR § 1.1 |  | 73                 | -20*                              | =        | 53        | x \$ 18.00 =                | -            | \$ 954.00                |  |  |  |
|  | INDEPENDE<br>(37 CFR § 1.1 |  | 2                  | -3**                              | =        | 0         | x \$ 80.00 =                |              | 0.00                     |  |  |  |
|  | MULTIPLE                   | DEPENDENT CI                           | AIMS (if           | applicable) (37 CFR §             | 1.16(d)) |           | x \$ 270.00 =               |              |                          |  |  |  |
|  |                            | ent de la                              | erioti<br>Projekti |                                   |          |           | BASIC FEE<br>(37 CFR §1.16) |              | \$ 710.00                |  |  |  |
|  | T                          | N/APC                                  | <b>51.</b> \$      | (1967)                            |          | Total of  | f above Calcula             | tions =      | \$1,664.00               |  |  |  |
|  |                            |  |                    | ity (Note 37 CFR 1.27             | ).       |           |                             |              |                          |  |  |  |
|  |                            | lms in excess of .<br>lependent claims |                    | r original patent.<br>nal patent. | TC       | OTAL =    |                             |              | \$1,664.00               |  |  |  |
| Small entity status: Applicant claims small entity status. See 37 CFR 1.27.  The Commissioner is hereby authorized to credit overpayments or charge the following fees to Deposit Account No. 08-3425.  a. |                            |  |                    |                                   |          |           |                             |              |                          |  |  |  |
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|  | gnature                    | In (A41-11 1                           |                    | Kull ffor                         |          |           |                             |              |                          |  |  |  |
|  | <del> </del>               | o.(Attorney/A                          | agent)             | 40,302/                           | ·<br>    |           |                             |              |                          |  |  |  |
|  | ate                        |  |                    | Decemb                            | 11 -     | 7000      |                             |              |                          |  |  |  |

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|  |               | fo                | r FY 20        | 001                          |               |              |   |   |                     |   |   |                  |                                       |                     |  |  |
|  | Pat           | ent fees are      | subject to     | annual re                    | vision.       |              |   |   |                     |   |   |                  |                                       |                     |  |  |
|  |               |                   |                |                              |               |              |   | tion Ñu   | mber                |   |   |                  | 08/961,08                             |                     |  |  |
|  |               |                   |                |                              |               |              | Filing I  |   |                     |   |   | October 30, 1997 |                                       |                     |  |  |
|  |               | <del></del>       | <del></del>    |                              |               |              |   | amed Inv  |                     |   |   |                  | Choi et a<br>Hines, J                 |                     |  |  |
|  |               |                   |                | <del></del>                  |               |              |   | Art Unit  | •                   |   |   |                  | 1641                                  | •                   |  |  |
| Total an   | ount of       | payment           |                | <del></del>                  | (\$)          | 1,794.00     |   |   | t Numbe             | ī                                       |   |                  | PB340P2                               | 2                   |  |  |
|  |               | ETHOD OF          | PAVMEN         | r (CHECK                     | 1`′           |              |   |   |                     |   |   |                  |                                       |                     |  |  |
| l. 🛛   |               | nmissioner is     |                |                              |               | ted          | 3. A  | FEE CALCULATION (CONTINUED)  3. ADDITIONAL FEES |                     |   |   |                  |                                       |                     |  |  |
|  |               | y overpayma       | nt to:         | 3-3425                       |               |              | Large E<br>Fee                                  | ntity<br>Fee                                    | Small En<br>Fee     | tity<br>Fee                             | Fee                                       |                  |                                       | F., n.:             |  |  |
| Number Deposit Account Human Genome Sciences, Inc.                                     |               |                   |                |                              |               | Code         | (S)   | Code  | ( <b>S</b> )        | Description                             |   |                  | Fee Paid                              |                     |  |  |
| Deposit<br>Nan   | Accou         | int <b>Huma</b>   | n Genon        | ne Scienc                    | es, Inc.      |              | 105   | 130   | 205                 | 65                                      | Surcharge - late f                        | iling of Oath    | or Declaration                        |                     |  |  |
| 1 vai:   | 110           |                   |                |                              |               |              | 127   | 50  | 227                 | 25                                      | Surcharge - late p                        | rovisional fil   | ing fee or cover                      |                     |  |  |
| ⊠ Cha  | arge A        | ny Additio        | nal Fee R      | Lequired                     |               |              | 139   | 130   | 139                 | 130                                     | Non-English spec                          | ification        |                                       |                     |  |  |
| Un   | der 37        | ČFR §§ 1.         | 16 and 1       | .17                          |               |              | 147   | 2,520   | 147                 | 2,520                                   | For filing a reque                        | -                |                                       |                     |  |  |
|  |               |                   |                |                              |               |              | 112   | 920   | 112                 | 920                                     | Requesting public<br>action               | cation of SIR    | prior to Examiner                     |                     |  |  |
|  |               | t claims sn       | nall entity    | status                       |               |              | 113   | 1,840   | 113                 | 1,840                                   | Requesting public<br>action               | cation of SIR    | after Examiner                        |                     |  |  |
| See  | 37 CI         | R 1.27            |                |                              |               |              | 115   | 110   | 215                 | 55                                      | Extension for rep                         |                  |                                       |                     |  |  |
| 2. Pa  | ment En       | closed:           |                |                              |               |              | 116<br>117                                      | 390<br>890                                      | 216<br>217          | 195<br>445                              | Extension for rep<br>Extension for rep    | -                | )                                     |                     |  |  |
| Ch   |               | Credit Card       | ☐ Money        | Order 🔯 0                    | Other*        |              | 118   | 1,390   | 217                 | 695                                     | Extension for rep                         | •                |                                       |                     |  |  |
| _  | ny deficie    | ncies or credit a | пу очеграуте   | nts in the fees              | or fee        |              | 128   | 1,890   | 228                 | 945                                     | Extension for rep                         | -                |                                       |                     |  |  |
| calculatio   | ons of Part   | s 1, 2 and 3 belo | ow to Deposit  | Account No.                  | 08-3425       |              | 119   | 310   | 219                 | 155                                     | Notice of Appeal                          |                  |                                       |                     |  |  |
|  |               | FEE               | CALCUL         | ATION                        |               |              | 120   | 310   | 220                 | 155                                     | Filing a brief in s                       |                  | anneal                                |                     |  |  |
| 1. BASI  | C FILIN       |                   |                |                              |               |              | 121   | 270   | 221                 | 135                                     | Request for oral l                        |                  | , , , , , , , , , , , , , , , , , , , |                     |  |  |
| Large  |               |                   |                |                              | 138           | 1,510        | 138   | 1,510   | Petition to institu | te a public us                          | e proceeding                              |                  |                                       |                     |  |  |
| Fee<br>Code  | Fee<br>(\$)   | Fee<br>Code       | Fee<br>(\$)    | Description                  | 1             | Paid         | l   |   |                     |   |   |                  |                                       |                     |  |  |
| 101  | 710           | 201               | 355            | Utility filing               |               | \$710        | 140   | 110   | 240                 | 55                                      | Petition to revive                        |                  | ,                                     |                     |  |  |
| 106<br>107   | 320<br>490    | 206<br>207        | 160<br>245     | Design filin<br>Plant filing |               |              | 141<br>142                                      | 1,240<br>1,240                                  | 241<br>242          | 620<br>620                              | Petition to revive<br>Utility issue fee ( |                  |                                       |                     |  |  |
| 108  | 710           | 208               | 355            | Reissue fili                 | ng fee        |              | 143   | 440   | 243                 | 220                                     | Design issue fee                          | ,                |                                       |                     |  |  |
| 114  | 150           | 214               | 75             | Provisional                  | filing fee    |              | 144<br>122                                      | 600<br>130                                      | 244<br>122          | 300<br>130                              | Plant issue fee<br>Petitions to the C     |                  |                                       | 130.00              |  |  |
|  | Subto         | tal (1)           |                |                              |               | \$710.00     | 123   | 50  | 123                 | 50                                      | Petitions related t                       |                  | applications                          | 130.00              |  |  |
|  |               |                   |                |                              |               |              | 126   | 240   | 126                 | 240                                     |   |                  | sclosure Statement                    |                     |  |  |
| 2. EXTRA   | A CLAIM       | I FEES            |                |                              |               |              | 581   | 40  | 481                 | 40                                      | Recording each p<br>(times number of      |                  | nent per property                     |                     |  |  |
|  |               |                   |                |                              |               | Fee          | 146   | 710   | 246                 | 355                                     | Filing a submissi                         | on after final   | rejection                             |                     |  |  |
|  |               |                   |                | Extra                        | from<br>below | Paid         |   |   |                     |   | (37 CFR 1.129(a)                          |                  |                                       | -                   |  |  |
| Total clai   | _             | 73                | - 20**         | 53                           | \$18.00       | \$954.00     | 149   | 710   | 249                 | 355                                     | CFR 1.129(b))                             |                  | to be examined (37                    |                     |  |  |
| Indep.clai<br>Multiple   | ims _         | 2                 | - 3**          | 0                            | 80.00         | \$0.00       | 179<br>169                                      | 710<br>190                                      | 279<br>169          | 355<br>900                              | Request for Conti<br>Request for expec    |                  |                                       |                     |  |  |
| Dependen   | ıt _          |                   |                | 1                            |               | <u> </u>     | l   |   |                     | - 30                                    | application                               |                  |                                       |                     |  |  |
| · · · · · ·  | E-ste         |                   | F. C.          | For                          | L             | L            | 8   | (specify)                                       | :                   |   |   |                  |                                       |                     |  |  |
| Large<br>Fee   | Entity<br>Fee | Small<br>Fee      | Entity<br>Fee  | Fee<br>Descripti             | on-           |              | Other fee                                       | (specify):                                      |                     |   |   |                  |                                       |                     |  |  |
| Code   | (\$)          | Code              | <b>(S)</b>     | 1                            |               |              | *p  | a ka na r                                       | . DUI P             | na Daile                                |   |                  |                                       |                     |  |  |
| 103  | 18            | 203               | <del>- 9</del> | Claims in                    | excess of 2   | 0            | Keauce  | u by Basi                                       | c Filing Fe         | e Paid                                  |   |                  |                                       |                     |  |  |
| 102  | 80            | 202               | 40             | •                            |               | excess of 3  | I   |   |                     |   |   |                  |                                       |                     |  |  |
| 104 270 204 135 Mutliple dependent claim<br>108 80 209 40 **Reissue independent claims |               |                   |                |                              |               |              | l   |   |                     |   |   |                  |                                       |                     |  |  |
| over original patent 110 18 210 9 **Reissue claims in excess of 20                     |               |                   |                |                              |               | excess of 20 |   |   |                     |   | Subtotal (3)                              |                  |                                       | \$130.00            |  |  |
| and over original patent   |               |                   |                |                              |               | int          |   |   |                     |   |   |                  |                                       |                     |  |  |
| Subtotal (2) (\$)954.00  |               |                   |                |                              |               |              |   |   |                     |   |   |                  |                                       |                     |  |  |
| Submitted By   |               |                   |                |                              |               |              |   | Complete (if applicable)                        |                     |   |   |                  |                                       |                     |  |  |
|  |               | e) Kenley         | K, Hoov        | er /                         | · · · ·       |              | Registration No.: 40,302 Telephone 301-610-5771 |   |                     |   |   |                  |                                       |                     |  |  |
|  |               | 1                 | 1              | 111                          | _             |              |   |   |                     |   |   |                  |                                       | 1                   |  |  |
| Signatu  | ire:          | Chr               | 12             | 112                          |               |              |   |   |                     |   |   |                  | Date (Z)                              | 11/2000             |  |  |

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Choi, et al. Issue Batch No.: H61

Application Serial No.: 08/961,083 Date Allowed: February 1, 2000

Filed: October 30, 1997 Art Unit: 1641

For: Streptococcus pneumoniae Antigens Examiner: Hines, J.

and Vaccines
Attorney Docket No.: PB340P2

#### <u>PETITION TO WITHDRAW APPLICATION FROM ISSUE</u> <u>UNDER 37 C.F.R. § 1.313(b)(1)</u>

Office of Petitions Washington, D.C. 20231

Attn: Marianne Morgan

Fax No.: 703-308-6916

Sir:

The Issue Fee for the above-identified application was paid on April 27, 2000, and was assigned Issue Batch No. H61. The above-identified application is scheduled to publish as United States Patent Number 6,159,469 on December 12, 2000.

Pursuant to 37 C.F.R. § 1.313(b)(1), Applicants request that the above-identified application be withdrawn from issue for abandonment in order to permit consideration of the amendment to the specification and claims that was filed concurrently with the Issue Fee on April 27, 2000, but disapproved for allegedly being an amendment under 37 C.F.R. § 1.312(b). Applicants submit herewith a copy of the postcard date-stamped by the Patent and Trademark Office on April 27, 2000, the Amendment Under 37 C.F.R. § 1.312, and the Issue Fee Transmittal. These documents evidence that the April 27, 2000 filing of the amendment was <u>not</u> after the date that the issue fee was paid, and accordingly, does not constitute an amendment under 37 C.F.R. § 1.312(b). Applicants additionally submit concurrently herewith a Continued Prosecution Application (CPA). Request Transmittal Under 37 C.F.R. § 1.53(d); and (b) Fee Transmittal.

The fee required with this Petition under 37 C.F.R. § 1.313(b)(1) is estimated to be \$130.00 under 37 C.F.R. § 1.17(i). Please charge the required fee and any other fee deemed necessary to Deposit Account No. 08-3425.

Date: December 11, 7000

Respectfully submitted,

enley K. Hoover (Reg. No. 40,302)

Attorney for Applicants

Human Genome Sciences, Inc.

9410 Key West Avenue Rockville, MD 20850 Telephone: (301) 610-5771

**Enclosures** 

Telecopier Transmission Certificate

Send date: December 11, 2000

I hereby certify that this paper and the attachments hereto are being sent by telecopier transmission to **703-308-6916** on the above-indicated date addressed to:

Marianne Morgan - Office of Petitions U.S. Patent and Trademark Office Washington, D.C. 20231

Name: Brenda Allen

Date

### HUMAN GENOME SCIENCES, IN

## Please date stamp and return to addressee on reverse side

Application of: Choi et al.

Application Number: 08/961,083

Filed: October 30, 1997

Title: Streptococcus pneumoniae Antigens

And Vaccines

Group Art Unit: 1641 Examiner: Hines, J.

Attny. Docket No.: PB340P2

### Documents Filed Via Hand Delivery on April 27,

1. Postcard (1)

2. Amendment Under 37 C.F.R. § 1.312

3. Fee Transmittal Sheet, with appropriate fee (in dupl.)

4. Statement under 37 C.F.R. §§ 1.821-1.825

5. Substitute Sequence Listing in paper and computer readable form (6 pages)

6. Issue Fee Transmittal, with appropriate fee (in dupl.)

MSM/CB/mpb

Attn.: Legal Dept.

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Choi et al.

Application Number: 08/961,083

Group Art Unit: 1641

Filed: October 30, 1997

Examiner: Hines, J.

Title: Streptococcus pneumoniae Antigens

And Vaccines

Attny. Docket No.: PB340P2

#### AMENDMENT UNDER 37 C.F.R. § 1.312

**BOX: AF** 

Assistant Commissioner for Patents

Washington, D.C. 20231

Sir:

In response to the Notice of Allowance dated 01 February 2000 and in accordance with Rule 312 of the Rules of Practice, please consider the following amendments and remarks. Applicants submit concurrently herewith: (a) a Substitute Sequence Listing in paper and computer readable form; (b) a Statement under 37 C.F.R. §§ 1.821-1.825; (c) an Issue Fee Transmittal, with appropriate fee; and (d) a Fee Transmittal Sheet, with appropriate fee.

#### Amendments

#### In the title

Please delete the current title and replace therefor -- Streptococcus pneumoniae SP036 polynucleotides, polypeptides, antigens and vaccines ---

#### In the specification

Please amend the specification as follows:

Page 1, after the title, please insert -- This application claims benefit of 35 U.S.C. section 119(e) based on copending U.S. Provisional Application Serial No. 60/029,960, filed Page 3, lines 17-18, please delete "sequences shown as SEQ ID NO:2, SEQ ID NO:4, SEQ ID NO:6, and so on through SEQ ID NO:226" and replace therefor -- sequence shown as SEQ ID NO:2 --.

Line 21, please delete "any of the amino acid sequences of the polypeptides" and replace therefor -- the amino acid sequence of the polypeptide --.

Lines 22-23, please delete "any of the amino acid sequences of the polypeptides" and replace therefor -- the amino acid sequence of the polypeptide--.

Page 4, line 5, please delete "any of the polypeptides" and replace therefor -- the polypeptide--.

Page 5, line 10, please delete "one or more of the polynucleotides or polypeptides" and replace therefor -- the polynucleotide and polypeptide--.

Line 22, please delete "amino acid sequences" and replace therefor -- the amino acid sequence--.

Line 23-24, please delete "amino acid sequences" and replace therefor --the amino acid sequence--.

Lines 28-29, please delete ", SEQ ID NO:3, SEQ ID NO:5, and so on through SEQ ID NO:225) which are" and replace therefor -- ) which is --.

Page 7, line 16, please delete "of one or more of the *S. pneumoniae* polypeptides" and replace therefor -- the *S. pneumoniae* polypeptide--.

Line 26, please delete "113 open reading frames (ORFs)" and replace therefor -- one open reading frame (ORF)--.

Line 31, please delete "polypeptides" and replace therefor --polypeptide--.

Line 32, please delete "each" and replace therefor -- the--.

Line 34, please delete "each" and replace therefor --the--.

Line 36, please delete "SP126" and replace therefor -- SP036--.

Line 37, please delete "126" and replace therefor --036--.

Line 38, please delete "SP126" and replace therefor -- SP036--.

Page 8, line 1, please delete "SEQ ID NO:223" and replace therefor -SEQ ID NO:1--.

Line 2, please delete "SEQ ID NO:224" and replace therefor --SEQ ID NO:2--.

Lines 8-9, please delete "each of the S. pneumoniae polypeptides" and replace therefor -- the S. pneumoniae polypeptide--.

Line 9, please delete "Each" and replace therefor -- The--.

Line 16, please delete "Lys-1 to Ile-10" of SP001, represents a peptide comprising the lysine at position 1 in SEQ ID NO:2 through and including the isoleucine at position 10 in SEQ ID NO:2, but may include more or fewer residuce than those 10" and replace therefor -- "Arg-10 to Arg-17" of SP036, represents a peptide comprising the arginine at position 1 in SEQ ID NO:2 through and including the arginine at position 17 in SEQ ID NO:2, but may include more or fewer residues than those 8.--

Line 24, please delete "each" and replace therefor --the--.

Line 37, please delete "many of the ORFs disclosed herein were" and replace therefor -- the ORF disclosed herein was--.

Page 11, line 8, please delete "a number of the disclosed ORFs" and replace therefor - the disclosed ORF--.

Lines 14-16, please delete "polypeptides having the amino acid sequences described in Table 1 and shown as SEQ ID NO:2, SEQ ID NO:4, SEQ ID NO:6, and so on through SEQ ID NO:226, which were" and replace therefor --polypeptide having the amino acid sequence described in Table 1 and shown as SEQ ID NO:2, which was--.

Page 12, lines 30-33, please delete ",SEQ ID NO:3, SEQ ID NO:5, and so on through SEQ ID NO:225; DNA molecules comprising the coding sequences for the polypeptides described in Table 1 and shown as SEQ ID NO:2, SEQ ID NO:4, SEQ ID NO:6, and so on through SEQ ID NO:226;" and replace therefor --; DNA molecules comprising the coding sequences for the polypeptide described in Table 1 and shown as SEQ ID NO:2;--.

Page 13, line 2, please delete "any one of those" and replace therefor --that--.

Line 13, please delete "most, if not all, of a" and replace therefor --the--.

Line 17, please delete "nucleotide sequences identified in Table 1 are provided as

SEQ ID NO:1, SEQ ID NO:3, SEQ ID NO:5, and so on through SEQ ID NO:225," and replace therefor --nucleotide sequence identified in Table 1 is provided as SEQ ID NO:1,--.

Line 23, please delete "polyeptides" and replace therefor -polypeptide--.

Line 26, please delete "each" and replace therefor –the--.

Line 28, please delete "polypeptides" and replace therefor -polypeptide--.

Page 14, line 11, please delete "most, if not all, of".

Line 14, please delete "sequences" and replace therefor -- sequence--.

Line 24, please delete "SEQ ID NO:3, SEQ ID NO:5, and so on through SEQ ID NO:225."

Page 15, line 1, please delete "residues" and replace therefor --residue--.

Line 16, please delete "residues" and replace therefor --residue--.

Lines 30-31, please delete "(e.g., another sequence selected from Table 1)".

Line 34, please delete "polypeptides" and replace therefor --polypeptide--.

Page 16, line 11, please delete "substitution" and replace therefor -substitutions--.

Line 17, please delete "any of the amino acid sequences of the polypeptides" and replace therefor -- the amino acid sequence of the polypeptide --.

Line 19, please delete "any of the nucleotide sequences" and replace therefor -- the nucleotide sequence--.

Line 36, please delete "some of the nucleic acid sequences" and replace therefor -- the nucleic acid sequence--.

Page 17, line 23, please delete "sequences" and replace therefor -- sequence--.

Line 34, please delete "these nucleotide sequences" and replace therefor -- the nucleotide sequence--.

Page 21, lines 24-25, please delete "sequences described in Table 1, and shown as SEQ ID NO:2, SEQ ID NO:4, SEQ ID NO:6, and so on through SEQ ID NO:226" and replace therefor --sequence described in Table 1, and shown as SEQ ID NO:2--.

Line 34, please delete "polypeptides" and replace therefor --polypeptide--.

Page 22, line 3, please delete "epitopes for each polypeptide is delineated" and replace therefor --epitopes for the polypeptide are delineated--.

Line 10, please delete "polypeptides" and replace therefor --polypeptide--.

Line 14, please delete "polypeptides" and replace therefor --polypeptide--.

Line 15, please delete "any one of the polypeptides" and replace therefor -- the polypeptide--.

Page 23, line 7, please delete "sequences shown in Table 1 may have on" and replace therefor --sequence shown in Table 1 may have one--.

Page 25, line 15, please delete "sequences" and replace therefor -- sequence--.

Line 20, please delete "polypeptides" and replace therefor --polypeptide--.

Page 29, line 18, please delete "sequences" and replace therefor --sequence--.

Page 32, line 4, please delete "polypeptides" and replace therefor --polypeptide--.

Page 36, line 26, please delete "more than one of the S. pneumoniae polypeptides" and replace therefor -- the S. pneumoniae polypeptide--.

Line 27, please delete "one or more, for example 2 to 10, of the S. pneumoniae polypeptides" and replace therefor -- the S. pneumoniae polypeptide--.

Line 35, please delete "ofS." and replace therefor --of S. --.

Line 35, please delete "that" and replace therefor --the--.

Page 37, line 1, please delete "one or more the S. pneumoniae polypeptides" and replace therefor -- the S. pneumoniae polypeptide--.

Line 2, please delete "the S. pneumoniae polypeptides" and replace therefor --the S. pneumoniae polypeptide--.

Page 41, line 32, please delete "sequences" and replace therefor --sequence--.

Line 41, please delete "polypeptides" and replace therefor --polypeptide--.

Line 37, please delete "polypeptides" and replace therefor --polypeptide--.

Page 42, line 8, please delete "polypeptides" and replace therefor -polypeptide--.

Line 15, please delete "NO:227 through SEQ ID NO:452" and replace therefor -- NO:3 thorugh SEQ ID NO:4--

Line 20, please delete "sequences" and replace therefor --sequence--.

Page 43, line 4, please delete "4 C" and replace therefor --4°C--.

Line 24, please delete "sequences" and replace therefor -- sequence--.

Line 28, please delete "Each of the polynucleotides" and replace therefor -- The polynucleotide--.

Lines 30-34, please delete "These pQE10 plasmids containing the DNAs of Table 1, except SP023, SP042, SP054, SP063, SP081, SP092, SP114, SP122, SP123, SP126, and SP127, were deposited with the ATCC as a pooled deposit as a convenience to those of skill in the art. This pooled deposit was desposited on October 16, 1997 and given ATCC Deposit No. 209369. Those of ordinary skill in the art appreciate that isolating an individual plasmid from the pooled deposit is trivial provided the information and reagents described herein. Each of the deposited clones is capable of expressing its encoded *S. pneumoniae* polypeptide."

Page 47, line 18, after "incorporated by reference" please insert --; however, U.S. Provisional Application Serial No. 60/029,960, filed October 31, 1996, is not incorporated by reference.--

Please delete Table 1, Table 2 and Table 3 at pages 48-110 and replace therefor with the following new Tables 1, 2 and 3:

#### SP036 nucleotide (SEQ ID NO:1)

TTCTTACGAGTTGGGACTGTATCAAGCTAGAACGGTTAAGGAAAATAATCGTGTTTCCTATATAGATGGAAAACA AGCGACGCAAAAAACGGAGAATTTGACTCCTGATGAGGTTAGCAAGCGTGAAGGAATCAATGCTGAGCAAATCGT CATCAAGATAACAGACCAAGGCTATGTCACTTCACATGGCGACCACTATCATTATTACAATGGTAAGGTTCCTTA TGACGCTATCATCAGTGAAGAATTACTCATGAAAGATCCAAACTATAAGCTAAAAGATGAGGATATTGTTAATGA GGTCAAGGGTGGATATGTTATCAAGGTAGATGGAAAATACTATGTTTACCTTAAGGATGCTGCCCACGCGGATAA CGTCCGTACAAAAGAGGAAATCAATCGACAAAAACAAGAGCATAGTCAACATCGTGAAGGTGGAACTCCAAGAAA CGATGGTGCTGTTGCCTTGGCACGTTCGCAAGGACGCTATACTACAGATGATGGTTATATCTTTAATGCTTCTGA TATCATAGAGGATACTGGTGATGCTTATATCGTTCCTCATGGAGATCATTACCATTACCATTCCTAAGAATGAGTT ATCAGCTAGCGAGTTGGCTGCAGAAGCCTTCCTATCTGGTCGAGGAAATCTGTCAAATTCAAGAACCTATCG CCGACAAAATAGCGATAACACTTCAAGAACAAACTGGGTACCTTCTGTAAGCAATCCAGGAACTACAAATACTAA CACAAGCAACAACAACAACAACTAACAGTCAAGCAAGTCAAAGTAATGACATTGATAGTCTCTTGAAACAGCTCTA CAAACTGCCTTTGAGTCAACGACATGTAGAATCTGATGGCCTTGTCTTTGATCCAGCACAAATCACAAGTCGAAC AGCTAGAGGTGTTGCAGTGCCACACGGAGATCATTACCACTTCATCCCTTACTCTCAAATGTCTGAATTGGAAGA ACGAATCGCTCGTATTATTCCCCTTCGTTATCGTTCAAACCATTGGGTACCAGATTCAAGGCCAGAACAACCAAG TCCACAACCGACTCCGGAACCTAGTCCAGGCCCGCAACCTGCACCAAATCTTAAAATAGACTCAAATTCTTCTTT GGTTAGTCAGCTGGTACGAAAAGTTGGGGAAGGATATGTATTCGAAGAAAAGGGCATCTCTCGTTATGTCTTTGC GAAAGATTTACCATCTGAAACTGTTAAAAATCTTGAAAGCAAGTTATCAAAACAAGAGAGTGTTTCACACACTTT AACTGCTAAAAAAGAAATGTTGCTCCTCGTGACCAAGAATTTTATGATAAAGCATATAATCTGTTAACTGAGGC TCATAAAGCCTTGTTTGNAAATAAGGGTCGTAATTCTGATTTCCAAGCCTTAGACAAATTATTAGAACGCTTGAA TGATGAATCGACTAATAAAGAAAAATTGGTAGATGATTTATTGGCATTCCTAGCACCAATTACCCATCCAGAGCG ACTTGGCAAACCAAATTCTCAAATTGAGTATACTGAAGACGAAGTTCGTATTGCTCAATTAGCTGATAAGTATAC AACGTCAGATGGTTACATTTTTGATGAACATGATAATCAGTGATGAAGGAGATGCATATGTAACGCCTCATAT GGGCCATAGTCACTGGATTGGAAAAGATAGCCTTTCTGATAAGGAAAAAGTTGCAGCTCAAGCCTATACTAAAGA AAAAGGTATCCTACCTCCATCTCCAGACGCAGATGTTAAAGCAAATCCAACTGGAGATAGTGCAGCAGCTATTTA CAATCGTGTGAAAGGGGAAAAACGAATTCCACTCGTTCGACTTCCATATATGGTTGAGCATACAGTTGAGGTTAA AAACGGTAATTTGATTATTCCTCATAAGGATCATTACCATAATATTAAATTTGCTTGGTTTGATGATCACACATA CAAAGCTCCAAATGGCTATACCTTGGAAGATTTGTTTGCGACGATTAAGTACTACGTAGAACACCCTGACGAACG TAAGAACTTCAAAGCGGATGAAGAGCCAGTAGAGGAAACACCTGCTGAGCCAGAAGTCCCTCAAGTAGAGACTGA AACAGAAACTCTAGCTGGTTTACGAAATAATTTGACTCTTCAAATTATGGATAACAATAGTATCATGGCAGAAGC 

#### SP036 amino acid (SEQ ID NO:2)

SYELGLYQARTVKENNRVSYIDGKQATQKTENLTPDEVSKREGINAEQIVIKITDQGYVTSHGDHYHYYNGKVPY DAIISEELLMKDPNYKLKDEDIVNEVKGGYVIKVDGKYYVYLKDAAHADNVRTKEEINRQKQEHSQHREGGTPRN DGAVALARSQGRYTTDDGYIFNASDIIEDTGDAYIVPHGDHYHYIPKNELSASELAAAEAFLSGRGNLSNSRTYR RQNSDNTSRTNWVPSVSNPGTTNTNTSNNSNTNSQASQSNDIDSLLKQLYKLPLSQRHVESDGLVFDPAQITSRT ARGVAVPHGDHYHFIPYSQMSELEERIARIIPLRYRSNHWYPDSRPEQPSPQPTPEPSPGPQPAPNLKIDSNSSL VSQLVRKVGEGYVFEEKGISRYVFAKDLPSETVKNLESKLSKQESVSHTLTAKKENVAPRDQEFYDKAYNLLTEA HKALFXNKGRNSDFQALDKLLERLNDESTNKEKLVDDLLAFLAPITHPERLGKPNSQIEYTEDEVRIAQLADKYT TSDGYIFDEHDIISDEGDAYVTPHMGHSHWIGKDSLSDKEKVAAQAYTKEKGILPPSPDADVKANPTGDSAAAIY NRVKGEKRIPLVRLPYMVEHTVEVKNGNLIIPHKDHYHNIKFAWFDDHTYKAPNGYTLEDLFATIKYYVEHPDER PHSNDGWGNASEHVLGKKDHSEDPNKNFKADEEPVEETPAEPEVPQVETEKVEAQLKEAEVLLAKVTDSSLKANA TETLAGLRNNLTLQIMDNNSIMAEAEKLLALLKGSNPSSVSKEKIN

## Table 2 S. pneumoniae Antigenic Epitopes

#### SPO36

Arg-10 to Arg-17; Lys-29 to Ser-39; Ser-140 to Ala-153; Arg-158 to Tyr-169; Asp-175 to Ala-183; Gly-216 to Asn-236; Ala-261 to Leu-270; Arg-282 to Phe-291; and Thr-297 to Ala-305; Pro-342 to Gln-362; Phe-455 to Asp-463; His-497 to Thr-511; Ala-521 to Gly-529; Ile-537 to Val-546; Ile-556 to Ala-568; Pro-581 to Ser-595; Glu-670 to Ala-685; Ser-696 to Ala-705 and Leu-782 to Ser-791

#### Table 3

| Primer      | S. pneumoniae ORF Cloning Primers        |          |
|-------------|--|----------|
| Name SEQ ID | Sequence                                 | RE       |
| SP036A NO:3 | AGTCGGATCCTTCTTACGAGTTGGGACTGTATCAAGC    | Bam HI   |
| SP036B NO:4 | AGTCAAGCTTGTTTATTTTTTCCTTACTTACAGATGAAGG | Hind III |

Please replace the pages of the Sequence Listing at pages 111-388 of the specification with the Substitute Sequence Listing (6 pages, numbered 1-6) submitted herewith.

Please renumber the pages accordingly.

#### In the claims:

Please amend the claims as follows:

- -- 198. (Amended) An isolated nucleic acid molecule comprising a polynucleotide selected from the group consisting of:
  - (a) a polynucleotide encoding amino acids 1 to 796 of SEQ ID NO:[56]2;
  - (b) a polynucleotide encoding amino acids 2 to 796 of SEQ ID NO: [56]2;
- (c) a polynucleotide encoding an epitope-bearing portion of amino acid residues 1 to 796 of SEQ ID NO: [56]2;
- (d) a polynucleotide probe encoding at least 15 contiguous amino acid residues of amino acid residues 1 to 796 of SEQ ID NO: [56]2;
- (e) a polynucleotide consisting of at least 50 contiguous nucleotides of nucleotides 1-2389 of SEQ ID NO: [55]1; and

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- (f) a polynucleotide completely complementary to a polynucleotide in (a), (b), (c), (d), or (e) above.
- 205. (Amended) The isolated nucleic acid molecule of claim 199, wherein said polynucleotide is SEQ ID NO: [55]1.
- 206. (Amended) The isolated nucleic acid molecule of claim 201, wherein said epitopebearing portion comprises amino residues Arg-10 to Arg-17 of SEQ ID NO: [56]2.
- 207. (Amended) The isolated nucleic acid molecule of claim 201, wherein said epitope-bearing portion comprises amino residues Lys-29 to Ser-39 of SEQ ID NO: [56]2.
- 208. (Amended) The isolated nucleic acid molecule of claim 201, wherein said epitopebearing portion comprises amino residues Ser-140 to Ala-153 of SEQ ID NO: [56]2.
- 209. (Amended) The isolated nucleic acid molecule of claim 201, wherein said epitope-bearing portion comprises amino residues Arg-158 to Tyr-169 of SEQ ID NO: [56]2.
- 210. (Amended) The isolated nucleic acid molecule of claim 201, wherein said epitope-bearing portion comprises amino residues Asp-175 to Ala-183 of SEQ ID NO: [56]2.
- 211. (Amended) The isolated nucleic acid molecule of claim 201, wherein said epitope-bearing portion comprises amino residues Gly-216 to Asn-236 of SEQ ID NO: [56]2.
- 212. (Amended) The isolated nucleic acid molecule of claim 201, wherein said epitope-bearing portion comprises amino residues Ala-261 to Leu-270 of SEQ ID NO: [56]2.
- 213. (Amended) The isolated nucleic acid molecule of claim 201, wherein said epitope-bearing portion comprises amino residues Arg-282 to Phe-291 of SEQ ID NO: [56]2.
- 214. (Amended) The isolated nucleic acid molecule of claim 201, wherein said epitope-bearing portion comprises amino residues Thr-297 to Ala-305 of SEQ ID NO: [56]2.

- 215. (Amended) The isolated nucleic acid molecule of claim 201, wherein said epitope-bearing portion comprises amino residues Pro-342 to Gln-362 of SEQ ID NO: [56]2.
- 216. (Amended) The isolated nucleic acid molecule of claim 201, wherein said epitopebearing portion comprises amino residues Phe-455 to Asp-463 of SEQ ID NO: [56]2.
- 217. (Amended) The isolated nucleic acid molecule of claim 201, wherein said epitope-bearing portion comprises amino residues His-497 to Thr-511 of SEQ ID NO: [56]2.
- 218. (Amended) The isolated nucleic acid molecule of claim 201, wherein said epitope-bearing portion comprises amino residues Ala-521 to Gly-529 of SEQ ID NO: [56]2.
- 219. (Amended) The isolated nucleic acid molecule of claim 201, wherein said epitope-bearing portion comprises amino residues Ile-537 to Val-546 of SEQ ID NO: [56]2.
- 220. (Amended) The isolated nucleic acid molecule of claim 201, wherein said epitope-bearing portion comprises amino residues Ile-556 to Ala-568 of SEQ ID NO: [56]2.
- 221. (Amended) The isolated nucleic acid molecule of claim 201, wherein said epitope-bearing portion comprises amino residues Pro-581 to Ser-595 of SEQ ID NO: [56]2.
- 222. (Amended) The isolated nucleic acid molecule of claim 201, wherein said epitopebearing portion comprises amino residues Glu-670 to Ala-685 of SEQ ID NO: [56]2.
- 223. (Amended) The isolated nucleic acid molecule of claim 201, wherein said epitope-bearing portion comprises amino residues Ser-696 to Ala-705 of SEQ ID NO: [56]2.
- 224. (Amended) The isolated nucleic acid molecule of claim 201, wherein said epitope-bearing portion comprises amino residues Leu-782 to Ser-791 of SEQ ID NO: [56]2.

- 225. (Amended) The isolated nucleic acid molecule of claim 202, wherein said polynucleotide encodes at least 30 contiguous amino acid residues of amino acid residues 1 to 796 of SEQ ID NO: [56]2.
- 226. (Amended) The isolated nucleic acid molecule of claim 203, wherein said polynucleotide consists of at least 100 contiguous nucleotides of nucleotides 1-2389 of SEQ ID NO: [55]1.
- 237. (Amended) An isolated polypeptide comprising a member selected from the group consisting of:
  - (a) a polypeptide of amino acid residues 1 to 796 of SEQ ID NO: [56]2;
  - (b) a polypeptide of amino acid residues 2 to 796 of SEQ ID NO: [56]2; and
- (c) an epitope-bearing portion of a polypeptide consisting of amino acid residues 1 to 796 of SEQ ID NO: [56]2.
- 241. (Amended) The isolated polypeptide of claim 240, wherein said epitope-bearing portion comprises amino residues Arg-10 to Arg-17 of SEQ ID NO: [56]2.
- 242. (Amended) The isolated polypeptide of claim 240, wherein said epitope-bearing portion comprises amino residues Lys-29 to Ser-39 of SEQ ID NO: [56]2.
- 243. (Amended) The isolated polypeptide of claim 240, wherein said epitope-bearing portion comprises amino residues Ser-140 to Ala-153 of SEQ ID NO: [56]2.
- 244. (Amended) The isolated polypeptide of claim 240, wherein said epitope-bearing portion comprises amino residues Arg-158 to Tyr-169 of SEQ ID NO: [56]2.
- 245. (Amended) The isolated polypeptide of claim 240, wherein said epitope-bearing portion comprises amino residues Asp-175 to Ala-183 of SEQ ID NO: [56]2.
- 246. (Amended) The isolated polypeptide of claim 240, wherein said epitope-bearing portion comprises amino residues Gly-216 to Asn-236 of SEQ ID NO: [56]2.

- 247. (Amended) The isolated polypeptide of claim 240, wherein said epitope-bearing portion comprises amino residues Ala-261 to Leu-270 of SEQ ID NO: [56]2.
- 248. (Amended) The isolated polypeptide of claim 240, wherein said epitope-bearing portion comprises amino residues Arg-282 to Phe-291 of SEQ ID NO: [56]2.
- 249. (Amended) The isolated polypeptide of claim 240, wherein said epitope-bearing portion comprises amino residues Thr-297 to Ala-305 of SEQ ID NO: [56]2.
- 250. (Amended) The isolated polypeptide of claim 240, wherein said epitope-bearing portion comprises amino residues Pro-342 to Gln-362 of SEQ ID NO: [56]2.
- 251. (Amended) The isolated polypeptide of claim 240, wherein said epitope-bearing portion comprises amino residues Phe-455 to Asp-463 of SEQ ID NO: [56]2.
- 252. (Amended) The isolated polypeptide of claim 240, wherein said epitope-bearing portion comprises amino residues His-497 to Thr-511 of SEQ ID NO: [56]2.
- 253. (Amended) The isolated polypeptide of claim 240, wherein said epitope-bearing portion comprises amino residues Ala-521 to Gly-529 of SEQ ID NO: [56]2.
- 254. (Amended) The isolated polypeptide of claim 240, wherein said epitope-bearing portion comprises amino residues Ile-537 to Val-546 of SEQ ID NO: [56]2.
- 255. (Amended) The isolated polypeptide of claim 240, wherein said epitope-bearing portion comprises amino residues Ile-556 to Ala-568 of SEQ ID NO: [56]2.
- 256. (Amended) The isolated polypeptide of claim 240, wherein said epitope-bearing portion comprises amino residues Pro-581 to Ser-595 of SEQ ID NO: [56]2.

- 257. (Amended) The isolated polypeptide of claim 240, wherein said epitope-bearing portion comprises amino residues Glu-670 to Ala-685 of SEQ ID NO: [56]2.
- 258. (Amended) The isolated polypeptide of claim 240, wherein said epitope-bearing portion comprises amino residues Ser-696 to Ala-705 of SEQ ID NO: [56]2.
- 259. (Amended) The isolated polypeptide of claim 240, wherein said epitope-bearing portion comprises amino residues Leu-782 to Ser-791 of SEQ ID NO: [56]2.
- 265. (Amended) The method of claim 17 wherein the polypeptide comprises amino acid residues 1 to 796 of SEQ ID NO:[56]2.
- 267. (Amended) The method of claim 17 wherein the polypeptide comprises an epitope-bearing portion of amino acid residues 1 to 796 of SEQ ID NO:[56]2.

#### Remarks

Claims 17-18 and 198-268 are allowed.

The title has been amended to more particularly identify the claimed invention.

The specification has been amended to: (a) delete text in the specification relating to the non-elected species and to cancel all sequence listings relating to the non-elected species; (b) recite sequence identifiers associated with the elected polynucleotides and polypeptides throughout the specification and the claims; (c) incorporate the Substitute Sequence Listing pursuant to 37 C.F.R. § 1.821 (c) and (d) renumber the pages of the claims accordingly. The above-mentioned amendments do not constitute new matter under 35 U.S.C. § 112.

Applicants submit that entry of the instant amendment does not raise new issues. Particularly, as disclosed in the specification, Applicant's invention is considered to be the sequence corresponding to an individual polynucleotide or fragment of the Streptococcus Pneumoniae genome (see, e.g., page 6, lines 16-19), as each polynucleotide fragment or ORF of the genome is separately patentable in its own right. This position is bolstered by the Patent Office's arguments in the record that the non-elected sequences are not related to the claimed invention, as demonstrated by the fact that the Patent Office has restricted and

withdrawn claims directed to non-elected sequences throughout the prosecution of the instant application.

Deletion of the reference to ATCC Deposit No. 209369 does not raise a new issue because the polynucleotide and polypeptide sequences disclosed in Table 1, as SEQ ID Nos: 1 and 2, were also available in the library deposited as ATCC Deposit No. 97755, or from DNA isolated from the same organism, such as the S. pneumoniae strain deposited with the ATCC as Deposit No. 55840. Both ATCC Deposit No. 97755 and ATCC Deposit No. 55840 are discussed in the instant specification at page 42, lines 1 to 4.

The sequences of the non-elected species are not required to support the elected claims under 35 U.S.C. §§ 101 and 112. Applicants point out that, as disclosed in the specification, a polynucleotide sequence corresponding to a single Streptococcus pneumoniae ORF can be used, for example, as a diagnostic probe to detect Streptococcus pneumoniae in a sample (see, e.g., page 46, lines 17-32). Applicants submit that on the priority date of the instant application, the skilled molecular biologist, enlightened by the teaching of the amended specification (i.e., the disclosure of the specification pending upon entry of the instant amendment) was more than capable of routinely generating the claimed polynucleotides and using the polynucleotides to express polypeptides, diagnose the presence of polynucleotides that hybridize to the claimed polynucleotides and to use the polypeptides of the invention to attenuate a Streptococcus infection. Further, amending the specification to delete text relating to the non-elected species and to cancel all sequence listings relating to the non-elected species, does not increase the scope of the claimed polynucleotides when compared to that prior to amending the specification. Further, deletion of disclosure relating to the non-claimed sequences does not constitute new matter.

#### Conclusion

Applicants respectfully request that the amendments and remarks of the present response be entered and made of record in the present application. Early notice to that effect

<sup>&</sup>lt;sup>1</sup> Applicants additionally point out that the publication and/or release of Applicants' proprietary information concerning the non-elected subject matter is not commensurate with the rights which would ultimately be granted to Applicants for the elected species.

is earnestly solicited. If, in the opinion of the Examiner, a telephone conference would expedite prosecution, the undersigned can be reached at the telephone number indicated below. If a fee is required in connection with this paper, please charge Deposit Account No. 08-3425 for the appropriate amount.

Respectfully submitted,

Date: 1000

Michelle S. Marks (Reg. No. 41,971)

Attorney for Applicants

Human Genome Sciences, Inc. 9410 Key West Avenue

9410 Key West Avenue Rockville, MD 20850 (301) 610-5761 (phone)

MSM/CCB

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## HUMAN GENOME SCIENCES LEGAL DEPARTMENT

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Fax: 301-309-8439

Date: December 11, 2000

Number of pages, including cover: 23

To:

Marianne Morgan Office of the Petitioner U.S. Patent and Trademark Office

703-308-6916

Phone:

From: Kenley K. Hoover

U.S. Patent Application No. 08/961,083

HGS Ref.: PB340P2

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In re Application of Gil H. Choi, et al. Application No. 08/961,083 Filed: October 30, 1997 Attorney Docket No. PB340P2

ON PETITION

This is a decision on the petition, filed December 11, 2000, under 37 CFR 1.313(c)(3) to withdraw the above-identified application from issue after payment of the issue fee.

The petition is GRANTED.

The above-identified application is withdrawn from issue in favor of a continued prosecution application (CPA) under 37 CFR 1.53(d).

The application is hereby withdrawn from issue.

Petitioner is advised that the issue fee paid on April 27, 2000 in the parent application is not refundable nor can it be applied towards any new Notice of Allowance which may issue on the CPA filed December 11, 2000.

Telephone inquiries should be directed to Marianne Morgan at (703) 306-3475.

The application is being forwarded to Technology Center 1600 for processing of the CPA.

Marianne E. Morgan

**Petitions Examiner** 

Office of Petitions

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## PATENT APPLICATION INFORMATION RETRIEVAL



| Search results for application number: 08/961,083 |   |                               |  |  |  |
|---|---|-------------------------------|--|--|--|
| Application<br>Number:                            |   | Customer<br>Number:           | 22195  |  |  |
| Filing or 371(c)<br>Date:                         | 10-30-1997  | Status:                       | Allowed – Notice of Allowance Mailed<br>– Issue Revision Completed |  |  |
| Application Type:                                 | Utility   | Status Date:                  | 05-20-2004   |  |  |
| Examiner Name:                                    | HINES, JANA A   | Location:                     | ELECTRONIC   |  |  |
| Group Art Unit:                                   |   | Location Date:                | -  |  |  |
| Confirmation<br>Number:                           |   | Earliest<br>Publication No:   |  |  |  |
| Attorney Docket<br>Number:                        | PB340P2   | Earliest<br>Publication Date: |  |  |  |
| Class/ Sub-Class:                                 | 424/165.1   | Patent Number:                | -  |  |  |
|   | GIL H. CHO!,<br>ROCKVILLE, MD (US)  | Issue Date of<br>Patent:      |  |  |  |
| Title Of Invention:                               | nvention: STREPTOCOCCUS PNEUMONIAE SP036 POLYNUCLEOTIDES, POLYPEPTIDES, ANTIGENS AND VACCINES |                               |  |  |  |

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| Date         | Contents Description                            |  |  |  |
| 07-08-2004   | Sequence Forwarded to Pubs on Tape              |  |  |  |
| 07-01-2004   | Workflow - File Sent to Contractor              |  |  |  |
| 05-21-2004   | Mail Notice of Allowance                        |  |  |  |
| 05-19-2004   | Issue Revision Completed                        |  |  |  |
| 05-19-2004   | Notice of Allowance Data Verification Completed |  |  |  |
| 05-19-2004   | Case Docketed to Examiner in GAU                |  |  |  |
| 05-17-2004   | Notice of Allowability                          |  |  |  |
| 04-14-2004   | Date Forwarded to Examiner                      |  |  |  |
| 03-24-2004   | Amendment after Final Rejection                 |  |  |  |
| 01-23-2004   | Mail Final Rejection (PTOL - 326)               |  |  |  |
| 01-23-2004   | Final Rejection                                 |  |  |  |
| 10-15-2003   | Date Forwarded to Examiner                      |  |  |  |
| 09-25-2003   | Response after Non-Final Action                 |  |  |  |
| 07-01-2003   | CRF Is Good Technically / Entered into Database |  |  |  |

| 06-25-2003 | Mail Non-Final Rejection  |
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| 06-25-2003 | Non-Final Rejection   |
| 04-23-2003 | Date Forwarded to Examiner  |
| 04-07-2003 | Response to Election / Restriction Filed                              |
| 03-06-2003 | Mail Restriction Requirement  |
| 03-05-2003 | Requirement for Restriction / Election                                |
| 01-09-2003 | Date Forwarded to Examiner  |
| 12-13-2002 | Response to a Letter to Comply with the Sequence Rules                |
| 11-14-2002 | Mail Letter Requiring CRF (Unreadable, Non-Compliant, Not Submitted)  |
| 11-14-2002 | CRF Diskette Unreadable / Did Not Comply / Required but Not Submitted |
| 09-18-2002 | Date Forwarded to Examiner  |
| 09-08-2002 | Response after Non-Final Action                                       |
| 08-09-2002 | Mail Notice of Informal or Non-Responsive Amendment                   |
| 12-11-2000 | Petition Entered  |
| 04-27-2000 | Workflow - Request for CPA - Begin                                    |
| 02-05-2002 | Date Forwarded to Examiner  |
| 04-27-2000 | Continuing Prosecution Application - Continuation (ACPA)              |
| 02-05-2002 | Express Abandonment (for Entry of CPA / RCE / Rule129)                |
| 05-12-2000 | Workflow - File Sent to Contractor                                    |
| 11-06-2001 | Case Docketed to Examiner in GAU                                      |
| 01-24-2001 | Petition Flag Set at Petitions Office                                 |
| 01-12-2001 | Official Search Conducted   |
| 01-12-2001 | Case Reported Lost  |
| 12-12-2000 | Recordation of Patent Grant Mailed                                    |
| 12-11-2000 | Sequence Moved to Public Database                                     |
| 11-24-2000 | Issue Notification Mailed   |
| 04-27-2000 | Mailroom Date of Issue Fee Payment                                    |
| 10-24-2000 | Mail Response to 312 Amendment (PTO-271)                              |
| 10-24-2000 | Response to Amendment under Rule 312                                  |
| 09-14-2000 | Date Forwarded to Examiner  |
| 04-27-2000 | Amendment after Notice of Allowance (Rule 312)                        |
| 07-30-2000 | Application Is Considered Ready for Issue                             |
| 04-27-2000 | Workflow - Incoming Correspondence - Finish                           |
| 06-23-2000 | Workflow - Query Request - Finish                                     |
| 06-06-2000 | Workflow - Query Request - Begin                                      |
| 05-19-2000 | Sequence Forwarded to Pubs on Tape                                    |
| 04-27-2000 | Workflow - Incoming Correspondence - Begin                            |
| 02-01-2000 | Mail Notice of Allowance  |
| 02-01-2000 | Notice of Allowance Data Verification Completed                       |
| 01-31-2000 | Notice of Allowability  |
| 12-17-1999 | Information Disclosure Statement (IDS) Filed                          |
| 12-17-1999 | Rule 47 / 48 Correction of Inventorship Papers Filed                  |
| 01-13-2000 | Date Forwarded to Examiner  |
| 12-17-1999 | Informal or Non-Responsive Amendment after Examiner Action            |
| 12-17-1999 | Response after Non-Final Action                                       |

| 12-17-1999 | Request for Extension of Time - Granted                  |
|------------|--|
| 06-22-1999 | Mail Non-Final Rejection                                 |
| 06-21-1999 | Non-Final Rejection                                      |
| 04-30-1999 | Information Disclosure Statement (IDS) Filed             |
| 04-30-1999 | Preliminary Amendment                                    |
| 05-19-1999 | Date Forwarded to Examiner                               |
| 04-30-1999 | Response to Election / Restriction Filed                 |
| 04-30-1999 | Request for Extension of Time - Granted                  |
| 03-03-1999 | Mail Restriction Requirement                             |
| 03-01-1999 | Requirement for Restriction / Election                   |
| 02-08-1999 | CRF Is Good Technically / Entered into Database          |
| 01-13-1999 | Information Disclosure Statement (IDS) Filed             |
| 01-25-1999 | CRF Disk Has Been Received by Preexam / Group / PCT      |
| 01-13-1999 | Preliminary Amendment                                    |
| 01-25-1999 | Date Forwarded to Examiner                               |
| 01-13-1999 | Response to Election / Restriction Filed                 |
| 01-13-1999 | Request for Extension of Time - Granted                  |
| 10-26-1998 | Mail Supplemental Restriction / Election Requirement     |
| 10-26-1998 | Supplemental Restriction                                 |
| 09-30-1998 | Mail Restriction Requirement                             |
| 09-30-1998 | Requirement for Restriction / Election                   |
| 09-17-1998 | Case Docketed to Examiner in GAU                         |
| 05-05-1998 | Case Docketed to Examiner in GAU                         |
| 04-25-1998 | Application Is Now Complete                              |
| 12-19-1997 | Notice MailedApplication Incomplete-Filing Date Assigned |
| 12-03-1997 | IFW Scan & PACR Auto Security Review                     |
| 12-19-1997 | Preexamination Location Change                           |
| 11-23-1997 | Initial Exam Team nn                                     |

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Mark J. Hyman (Reg. No. 46,789)

RE:

Application No. 08/961,083 (Atty. Docket No. PB340P2)

Per your request, enclosed are the last several papers filed in App. No. 08/961,083. What appears to have occurred is that we filed an amendment under 37 CFR 1.312 concurrently with the issue fee on April 27, 2000, but that amendment was (improperly) rejected as filed after payment of the issue fee. In response, we filed a petition to withdraw the case from issue together with a CPA requesting entry of the previous amendment. That petition was granted on December 11, 2000. We have nothing in our file since that date.

Please let me know if you need anything more. Thanks for your assistance.

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|-----------------|-------------------|----------------------|-------------------------|-----------------|
| 08/961,083      | 10/30/1997        | GIL H. CHOI          | PB340P2                 | 6931            |
| 22195           | 7590 08/09/2002   |                      |                         |                 |
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|                   |   |  | -   |   |                                  |
|                   | Not   | ice of Non-                            | Compliant Amendment (3  | 7 CFR 1.12                                  | (1)                              |
| the for<br>1238 ( | The amendment required un 0.G. 77, Sept. 19 | der 37 CFR 1.121,                      | is considered non-compliant t<br>as amended on September 8, 2000 (see 65 Fed  | pecause it has not b<br>I. Reg. 54603, Sept | een submitted in<br>8, 2000, and |
|                   | 1. The amend<br>37 CFR 1.12                 | dment does not inclu<br>l(b)(l)(ii).   | de a clean version of the replacement paragi  | raph(s)/section(s).                         |                                  |
| V                 | 2. The amend<br>37 CFR 1.12                 | lment does not inclu<br>1(b)(1)(iii)   | ide a marked-up version of the replacement p  | aragraph(s)/sectio                          | on(s).                           |
|                   | 3. The amend                                | iment does not inclu                   | nde a clean version of the amended claim(s).  | 37 CFR 1.121(c)(1)                          | <b>(i)</b>                       |
| d                 | 4. The amend                                | lment does not inclu                   | de a marked-up version of the amended claim   | n(s). 37 CFR 1.121                          | (c)(1)(ii)                       |
|                   | 5. Other.                                   |  |   | ···   |                                  |
|                   |   |  |   |   |                                  |
| V                 | with revised<br>may comme                   | 37 CFR 1.121 wince without entry       | ENT: Unless applicant re-submits the pret<br>thin ONE MONTH of the mail date of thi<br>of the originally proposed preliminary am<br>and this ONE MONTH time limit is not ex | s letter, examina<br>endment. This n        | tion on the merits               |
|                   | fide, applicated date of this               | nt is given a TIM<br>notice, whichever | N-FINAL ACTION: Since the above ment E PERIOD of ONE (1) MONTH or THI is longer, within which to supply the omis SIONS OF THIS TIME PERIOD MAY B                            | RTY (30) DAYS                               | from the mailing n in order to   |

For your convenience, attached to this correspondence is a copy of an informational flyer (MPEP Bookmark Bulletin on "Simplified Amendment Practice").

Legal Instruments Examiner



### HUMAN GENOME SCIENCES LEGAL DEPARTMENT

9410 Key West Avenue Rockville, MD 20850

Phone: 301-309-8504

Fax: 301-309-8439

### FAX COVER SHEET

DATE: September 9, 2002

TOTAL NUMBER OF PAGES:

3

TO: Examiner Jana Hines

**GAU 1645** 

United States Patent & Trademark Office

FAX NO.: (703) 308-4242

PHONE NO.: (703) 305-0487

FROM:

Mark J. Hyman (Reg. No. 46,789)

RE:

Application No. 08/961,083 (Atty. Docket No. PB340P2)

Attached please find the response we discussed by telephone this morning. Please let me know if you need anything more. Thanks for your assistance.

ML

If you experience any difficulty receiving this transmission, please contact Mark J. Hyman at (240) 314-1224.

The information contained in this facsimile message is information protected by attorney-client and/or the attorney/work product privilege. It is intended only for the use of the individual named above and the privileges are not waived by virtue of this having been sent by facsimile. If the person actually receiving this facsimile or any other reader of the facsimile is not the named recipient or the employee or agent responsible to deliver it to the named recipient, any use, dissemination, distribution or copying of the communication is strictly prohibited. If you have received this communication in error, please immediately notify us by telephone and return the original message to us at the above address via U.S. Postal Service.

VIA FACSIMILE SEPTEMBER 9, 2002

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Choi et al.

Atty. Docket: PB340P2

Application Serial No.: 08/961,083

Examiner: Hines, J.

Filed: January 3, 1997

Art Unit: 1645

For:

Streptococcus pneumoniae Antigens and Vaccines

#### REPLY TO NOTICE OF NON-COMPLIANT AMENDMENT (37 C.F.R. § 1.121)

Commissioner for Patents Washington, D.C. 20231

Sir:

Further to the undersigned's telephone conversation today with the Examiner, Applicants respectfully assert that the response to the Notice of Non-Compliant Amendment (37 C.F.R. § 1.121), dated August 9, 2002, was issued in error by the Office. In particular, the Rule 312 amendment in question was filed April 27, 2000, prior to the effective date of revised Rule 121. However, the amendment was erroneously disapproved by the Office as being submitted after payment of the issue fee, although the issue fee was actually paid on the same date as the amendment. After a successful petition to withdraw the case from issue, a Continuing Prosecution Application (CPA) was filed on December 11, 2000, requesting entry of the previously submitted amendment.

Thus, as discussed with the Examiner, since the amendment was submitted on April 27, 2000, and is in full compliance with the version of Rule 121 effective on that date, the instant Notice has been mailed in error and should be withdrawn. Applicants respectfully request that the amendments and remarks made in the amendment of April 27, 2000, be entered and made of record in the present application.

The Examiner is invited to call the undersigned at the phone number provided below if any further action by Applicants would expedite the examination of this application. No fee is believed due, but if a fee is required in connection with this paper, please charge Deposit Account No. 08-3425 for the appropriate amount.

Respectfully submitted,

Date: September 9, 2002

Mark J. Hyman (Reg. No. 46,789)

Attorney for Applicants

Human Genome Sciences, Inc. 9410 Key West Avenue Rockville, MD 20850 (240) 314-1224

#### CERTIFICATE OF TRANSMISSION UNDER 37 C.F.R. § 1.8

- 1. Fax Cover Sheet
- 2. Reply to Notice of Non-Compliant Amendment (37 C.F.R. § 1.121)

I hereby certify that the above-listed correspondence is being facsimile transmitted to the United States Patent and Trademark Office on September 9, 2002.

Mark J. Hyman

(Reg. No. 46,789)

Attorney for Applicants

Human Genome Sciences, Inc.

9410 Key West Avenue Rockville, MD 20850

Telephone: (240) 314-1224

PB340P2 2 of 2 Serial No: 08/961,083

#### Confirmation Report-Memory Send

: Sep-09-02 04:51pm

Tel line 1: 3013098439

Name

: HGS PATENT DEPT

Job number

: 754

Date

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: 7033084242

Document Pages

: 03

Start time

: Sep-09 04:50pm

End time

: Sep-09 04:51pm

Pages sent

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## HUMAN GENOME SCIENCES LEGAL DEPARTMENT

9410 Key West Avenue Rockville, MD 20850

Phone: 301-309-8504

Fax: 301-309-8439

#### **FAX COVER SHEET**

DATE: September 9, 2002

TOTAL NUMBER OF PAGES:

TO:

Examiner Jana Hines

GAU 1645 United States Patent & Trademark Office

FAX NO.: (703) 308-4242

PHONE NO.: (703) 305-0487

FROM:

Mark J. Hyman (Reg. No. 46,789)

RE:

Application No. 08/961,083 (Atty. Docket No. PB340P2)

Attached please find the response we discussed by telephone this morning. Please let me know if you need anything more. Thanks for your assistance.

If you experience any difficulty receiving this transmission, please contact Mark J. Hyman at (240) 314-1224.

The information commined in this faceimile measure is information protected by amorney-ellent and/or the attorney/work product privilege. It is intended only for the use of the individual named above and the privileges are not waived by virtue of this having been sent by faceimile. If the person actually receiving third receiving of the faceimile of the faceimile is not the named receives to the instead of prent, any use, dissemination, distribution or copying of the commingation is strictly prohibited. If you have releaved thus commingation is strictly prohibited. If you have releaved thus commingation is strictly prohibited. If you have releaved thus commingation in error, please string-distribution or copying of the return the original message to us at the above numbers of the later of the second prohibited.



### United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231 www.uspto.gov

| APPLICATION NO.           | FILING DATE       | FIRST NAMED INVENTOR   | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|---------------------------|-------------------|--|-------------------------|------------------|
| 08/961,083 10/30/1997     |                   | GIL H. CHOI  | PB340P2                 | 6931             |
| 22                        | 590 11/14/2002    | 500 ACA 1990 B C. R. Scattle Book  | 57.37                   | D.E.O.           |
|                           | NOME SCIENCES INC | RECEIVED   | EXAM                    |                  |
| 9410 KEY WE<br>ROCKVILLE, |                   | The state of the s | HINES, .                | JANA A           |
| ROCK VILLE,               | 14110 20000       | NOV 18 20021   | ART UNIT                | PAPER NUMBER     |
|                           |                   | KKH MJH  | 1645                    |                  |
|                           | -                 | hgs patent dept  | DATE MAILED: 11/14/2002 | 0()              |
|                           |                   | L. M.  |                         | X                |
|                           |                   | ~~~~   |                         |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

UNITED STATES DEPARTMENT OF COMMERCE **Patent and Trademark Office COMMISSIONER OF PATENTS AND TRADEMARKS** Washington, D.C. 20231

| SERIAL NUMBER | FILING DATE | FIRST NAMED APPLICANT |  | ATTORNEY DOCKET NO. |
|---------------|-------------|-----------------------|--|---------------------|
| 08/961,083    | 10/30/97    | Choi et al.           |  | PB340P2             |
|               |             | -                     |  |                     |

| <del></del> |
|-------------|
|             |
| APER NUMBER |
| 28          |
|             |

DATE MAILED:

#### Please find below a communication from the EXAMINER in charge of this application

Commissioner of Patents

- This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CAR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CAR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.
- Applicant is given ONE MONTH, or THIRTY DAYS, whichever is longer, from the mailing date of this letter within which to comply with the sequence rules, 37 CAR 1.821 -1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CAR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CAR 1.136(a). In no case may an applicant extend the period for reply beyond the SIX MONTH statutory period. Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.
- 3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is (703) 305-0487. The examiner can normally be reached on Monday-Thursday from 7:30-5:00 pm (Eastern Time) and 7:30-4:00 PM every other Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703)308-3909. The FAX phone number for group 1600 is (703)308-4242.

An inquiry of a general nature or relating to the status of the application should be directed to the group receptionist whose telephone number is (703)308-0196.

> LYNETTE R. F. SMITH SUPERVISORY PATENT EXAMINER **TECHNOLOGY CENTER 1600**

| A | p | plication | ن.O.ن | 08/96 | 1 | .083 |  |  |
|---|---|-----------|-------|-------|---|------|--|--|
|---|---|-----------|-------|-------|---|------|--|--|

## NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

| comply wi   | otide and/or amino acid sequence disclosure contained in this application does not the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the reason(s):  |
|-------------|---|
|             | 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998). |
|             | <ol><li>This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence<br/>Listing" as required by 37 C.F.R. 1.821(c).</li></ol>  |
|             | 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).   |
|             | 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."   |
|             | 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).   |
|             | 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).  |
| X<br>the    | 7. Other: The amendment of April 27, 2000 refers to a submitted CRF for the amended sequences, however no such form has been recieved by the office; therefor applicant is asked to resubmit CRF and associated information.  |
| Ар          | plicant Must Provide:   |
| $\boxtimes$ | An initial or <u>substitute</u> computer readable form (CRF) copy of the "Sequence Listing".  |
| $\boxtimes$ | An initial or <u>substitute</u> paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.   |
| X           | A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).  |

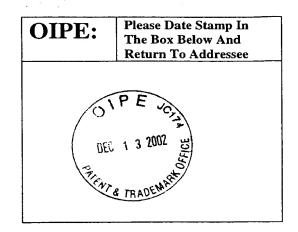
For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216 For CRF Submission Help, call (703) 308-4212

Patentin Software Program Support

## RETURN RECEIPT CARD

(MPEP § 503)



Application of:

Choi et al.

Docket No.: PB340P2

Application Serial No.: 08/961,083

Art Unit: 1645

Filed: October 30, 1997

Examiner: Jana A. Hines

Title: Streptococcus pneumoniae Antigens and

Vaccines

## The following documents were filed by Human Genome Sciences, Inc. via hand delivery on December 13, 2002:

- 1. Postcard;
- 2. Fee Transmittal Sheet (in duplicate);
- 3. Response to Notice to Comply With Sequence Regulations and Statement Under 37 C.F.R. 1.825;
- 4. Copy of Notice to Comply with Requirements; and
- 5. Substitute Sequence Listing in paper (6 pages) and computer readable (CRF) (1 disk) forms.

MJH/LJH/rmr

PTO/SB/17 (10-02)
Approved for use through 10/31/2002. OMB 0651-0032
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

| FEE TO AMONUTE AT   |   | Complete if Known             |              |         |                            |                                  |                                |                                       |
|---|---|-------------------------------|--------------|---------|----------------------------|----------------------------------|--------------------------------|---------------------------------------|
| FEE TRANSMITTAL   |   | Application Number 08/961,083 |              |         |                            |                                  | 083                            |                                       |
| for FY 2003   |   | Filing Date October 30, 1997  |              |         |                            | 30, 1997                         |                                |                                       |
|   |   | First                         | Name         | d inve  | ntor                       | Gil H. Cl                        | hoi et al.                     |                                       |
| Patent fees are subject to annual revision.                                     |   |                               | niner N      |         |                            | Jana A.                          | Hines                          |                                       |
| Applicant claims small entity status. See 37 CFR 1.27                           |   | Grou                          | p Art U      | nit     |                            | 1645                             |                                | · · · · · · · · · · · · · · · · · · · |
| TOTAL AMOUNT OF PAYMENT (\$) 0.00   |   | Attorr                        | ney Do       | cket N  | о.                         | PB340P                           | 2                              |                                       |
| METHOD OF PAYMENT (check all that apply)  | T   |                               |              | FE      | CALCU                      | L <b>ATION</b> (c                | ontinued)                      |                                       |
| Check Credit Money Other None   | 2 /   | DDITI                         | ONAL         |         |                            | ·                                |                                |                                       |
| Caro Coroer Coroer  | J. 7  |                               | UIVAL        |         | •                          |                                  |                                |                                       |
| Deposit Account   | Large   | Entity                        | Small        | Entity  |                            |                                  |                                | •                                     |
| Deposit<br>Account 08-3425  | Fee   | Fee                           | Fee          | Fee     | -                          | Fee Des                          | crintian                       |                                       |
| Number  | Code  | (\$)                          | Code         | (\$)    |                            | ree Des                          | enption                        | Fee Paid                              |
| Deposit Account Human Genome Sciences, Inc.                                     | 1051  | 130                           | 2051         | 65      | Surcharge                  | - late filing f                  | ee or oath                     |                                       |
| Name The Commissioner is hereby authorized to: (check all that apply)           | 1052  | 50                            | 2052         | 25      | Surcharge<br>sheet.        | - late provisi                   | ional filing fee or cover      |                                       |
| Charge fee(s) indicated below X Credit any overpayments                         | 1053  | 130                           | 1053         | 130     |                            | h specification                  |                                |                                       |
| Charge any additional fee(s) during the pendency of this                        |   |                               |              |         | •                          | •                                |                                |                                       |
| application   | 1812  | 2,520                         | 1812         |         | _                          | ,                                | parte reexamination            |                                       |
| Charge fee(s) indicated below, except for the filing fee                        | 1804  | 920*                          | 1804         | 920°    | Examiner a                 |                                  | of SIR prior to                |                                       |
| to the above-identified deposit account.  | 1805  | 1,840*                        | 1805         | 1,840*  | Requesting<br>Examiner a   | publication                      | of SIR after                   |                                       |
| FEE CALCULATION   | 1251  | 110                           | 2251         | 55      |                            |                                  | n first month                  |                                       |
| 1. BASIC FILING FEE   | 1252  | 400                           | 2252         | 200     | Extension f                | or reply with                    | n second month                 |                                       |
| Large Entity Small Entity   | 1253  | 920                           | 2253         | 460     | Extension f                | or reply withi                   | n third month                  |                                       |
| Fee Fee Fee Fee Fee Description Fee Paid  | 1254  | 1,440                         | 2254         | 720     | Extension f                | or reply withi                   | n fourth month                 |                                       |
| 1001 740 2001 370 Utility filing fee  | 1255  | 1,960                         | 2255         | 980     | Extension f                | or reply withi                   | n fifth month                  |                                       |
| 1002 330 2002 165 Design filing fee   | 1401  | 320                           | 2401         | 160     | Notice of A                | ppeal                            |                                |                                       |
| 1003 510 2003 255 Plant filing fee  | 1402  | 320                           | 2402         | 160     | -                          | ef in support                    |                                |                                       |
| 1004 740 2004 370 Reissue filing fee<br>1005 160 2005 80 Provisional filing fee | 1403<br>1451  | 280                           | 2403         | 140     |                            | r oral hearing                   |                                |                                       |
| 1005 160 2005 80 Provisional filing fee   | 1452  | 1,510<br>110                  | 1451<br>2452 | 55      | •                          | ristitute a pui<br>revive – unav | blic use proceeding            |                                       |
| SUBTOTAL (1) (\$) 0.00  | 1453  | 1,280                         | 2453         | 640     |                            | evive - uninte                   |                                |                                       |
| 2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE                                     | 1501  | 1,280                         | 2501         | 640     | Utility issue              | fee (or reiss                    | ue)                            |                                       |
| Extra Fee from<br>Claims below Fee Paid   | 1502  | 460                           | 2502         | 230     | Design issu                | e fee                            | ·                              |                                       |
| Total Claims 8 -20** = x = 0.00   | 1503  | 620                           | 2503         | 310     | Plant issue                | fee                              |                                |                                       |
| Independent 2 -3** = x = 0.00   | 1460  | 130                           | 1460         | 130     | Petitions to               | the Commis                       | sioner                         |                                       |
| Claims 2 3 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5                                  | 1807  | 50                            | 1807         | 50      | Processing                 | fee under 37                     | CFR 1.17(q)                    |                                       |
| Large Entity Small Entity   | 1806  | 180                           | 1806         | 180     | Submission                 | of Information                   | on Disclosure Stmt             |                                       |
| Fee Fee Fee Fee Fee Description   | 8021  | 40                            | 8021         | 40      |                            |                                  | ssignment per                  |                                       |
| Code (\$)   Code (\$)     Tee Description                                       |   |                               |              |         |                            |                                  | of properties) final rejection |                                       |
| 1201 84 2201 42 Independent claims in excess of 3                               | 1809  | 740                           | 2809         | 370     | (37 CFR 1.                 | 129(a))                          |                                |                                       |
| 1203 280 2203 140 Multiple dependent claim, if not paid                         | 1810  | 740                           | 2810         | 370     |                            | lditional inve<br>37CFR 1.129    |                                |                                       |
| 1204 84 2204 42 ** Reissue independent claims                                   | 1801  | 740                           | 2801         | 370     |                            |                                  | xamination (RCE)               |                                       |
| over original patent  1205 18 2205 9 ** Reissue claims in excess of 20          | 1802  | 900                           | 1802-        | 900     | Request for<br>of a design | expedited ex                     | xamination                     |                                       |
| and over original patent  | Other f   | ı<br>ee (spec                 | ify)         |         | or a design                | appiicalioi i                    | ł                              |                                       |
| SUBTOTAL (2) (\$) 0.00  | *Redu   | ced by E                      | asic Fil     | ing Fee | Paid                       | SUBTO                            | TAL (3) (\$)                   | 0.00                                  |
| **or number previously paid, if greater; For Reissues, see above                |   |                               |              |         |                            |                                  |                                |                                       |
| SUBMITTED BY  |   |                               |              |         |                            | Complete (                       | if applicable)                 |                                       |
| Name (Print/Type) Lin J. Hymel  | Registration No. (Attorney/Agent) 45,414 Telephone (301) 251-6015 |                               |              |         |                            |                                  |                                |                                       |
| Signature A August  | Date December 13, 2   |                               |              |         | 002                        |                                  |                                |                                       |

Docket No.: PB340P2

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

Choi et al.

Application No.: 08/961,083

Group Art Unit: 1645

Filed: October 30, 1997

Examiner: Jana A. Hines

For: Streptococcus pneumoniae Antigens and

Vaccines

## RESPONSE TO NOTICE TO COMPLY WITH SEQUENCE REGULATIONS AND STATEMENT UNDER 37 C.F.R. §1.825

Commissioner for Patents Washington, D.C. 20231

Sir:

In response to the Notice to Comply mailed November 14, 2002 (Paper No. 28),
Applicants submit herewith a Substitute Sequence Listing for the above captioned application. A
paper copy and a computer readable form of the original sequence listing, together with a
Statement Under 37 C.F.R. 1.821 and 1.825, were submitted with an Amendment on April 27,
2000, but the computer readable form apparently was not received by the Patent and Trademark
Office.

Applicants submit herewith a substitute computer readable form and a substitute paper copy of the sequence listing. The sequence listing filed on April 27, 2000 did not describe nucleotide 1368 ("n") of SEQ ID NO:1 or residue 456 ("Xaa") of SEQ ID NO:2, which is corrected in the attached Substitute Sequence Listing. Applicants hereby certify that the content of the paper copy and the computer readable form of the Substitute Sequence Listing submitted

herewith are the same. Applicants further certify that the amendments to the sequence listing are supported by the specification.

Respectfully submitted,

Dated: 13 December 2002

in J. Hymel

(Reg. No. 45,414)

Attorney for Applicants

Human Genome Sciences, Inc.

9410 Key West Avenue Rockville, MD 20850 (301) 251-6015 (phone)

MJH/LJH/rmr

# NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

| The nucleotide and/or amino acid sequence disclosure co  | contained     | in this | appl  | ication | does r | ot      |
|--|---------------|---------|-------|---------|--------|---------|
| comply with the requirements for such a disclosure as se | et forth in 3 | 37 C.F  | .R. 1 | 1.821 - | 1.825  | for the |
| following reason(s):                                     |               |         |       |         |        |         |

|          | 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998). |
|----------|---|
|          | 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).   |
|          | 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).   |
|          | 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."   |
|          | 5. The computer readable form that has been filed with this application has been found to be damaged<br>and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute<br>computer readable form must be submitted as required by 37 C.F.R. 1.825(d).   |
|          | 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).  |
| X<br>the | 7. Other: The amendment of April 27, 2000 refers to a submitted CRF for the amended sequences, however no such form has been recieved by the office; therefor applicant is asked to resubmit CRF and associated information.  |
| Ap       | plicant Must Provide:   |
| X        | An initial or <u>substitute</u> computer readable form (CRF) copy of the "Sequence Listing".  |
| X        | An initial or <u>substitute</u> paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.   |
|          | A statement that the content of the paper and computer readable copies are the same and, where applicable, include no-new matter, as required by 37-C.F.R1.821(e)-or-1.821(f) or-1.821(g)-or-1.825(b) or 1.825(d).  |
| For      | questions regarding compliance to these requirements, please contact:   |
|          | Rules Interpretation, call (703) 308-4216   |
|          | CRF Submission Help, call (703) 308-4212<br>entln Software Program Support  |
|          | onthi outtituto i togiuni ouppett   |

#### 340-SL-12-Dec-02 SEQUENCE LISTING

<110> Choi et. al. <120> Streptococcus pneumoniae Antigens and Vaccines <130> PB340P2 <140> 08/961,083 <141> 1997-10-30 <150> 60/029,960 <151> 1996-10-31 <160> 4 <170> PatentIn version 3.0 <210> 1 <211> 2389 <212> DNA <213> Streptococcus pneumoniae <220> <221> SITE <222> (1368)..(1368) <223> n equals a, c, g, or t

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|---|-------|
|   |       |
| tatagatgga aaacaagcga cgcaaaaaac ggagaatttg actcctgatg aggttagcaa         |       |
| gcgtgaagga atcaatgctg agcaaatcgt catcaagata acagaccaag gctatgtca          |       |
| ttcacatggc gaccactatc attattacaa tggtaaggtt ccttatgacg ctatcatca          | g 240 |

|                       |            | 340-SL-12          |            | ****       | 300              |
|-----------------------|------------|--------------------|------------|------------|------------------|
| tgaagaatta ctcatgaaag |            |                    |            |            | 300              |
| ggtcaagggt ggatatgtta |            |                    |            |            | 360              |
| tgcccacgcg gataacgtcc |            |                    |            | •          | 420              |
| tcaacatcgt gaaggtggaa |            |                    |            |            | 480              |
| aggacgctat actacagatg | atggttatat | ctttaatgct         | tctgatatca | tagaggatac | 540              |
| tggtgatgct tatatcgttc | ctcatggaga | tcattaccat         | tacattccta | agaatgagtt | 600              |
| atcagctagc gagttggctg | ctgcagaagc | cttcctatct         | ggtcgaggaa | atctgtcaaa | 660              |
| ttcaagaacc tatcgccgac | aaaatagcga | taacacttca         | agaacaaact | gggtaccttc | 7.20             |
| tgtaagcaat ccaggaacta | caaatactaa | cacaagcaac         | aacagcaaca | ctaacagtca | 780              |
| agcaagtcaa agtaatgaca | ttgatagtct | cttgaaacag         | ctctacaaac | tgcctttgag | 840              |
| tcaacgacat gtagaatctg | atggccttgt | ctttgatcca         | gcacaaatca | caagtcgaac | 900              |
| agctagaggt gttgcagtgc | cacacggaga | tcattaccac         | ttcatccctt | actctcaaat | 960              |
| gtctgaattg gaagaacgaa | tcgctcgtat | tattcccctt         | cgttatcgtt | caaaccattg | 1020             |
| ggtaccagat tcaaggccag | aacaaccaag | tccacaaccg         | actccggaac | ctagtccagg | 1080             |
| cccgcaacct gcaccaaatc | ttaaaataga | ctcaaattct         | tctttggtta | gtcagctggt | 1140             |
| acgaaaagtt ggggaaggat | atgtattcga | agaaaagggc         | atctctcgtt | atgtctttgc | 1200             |
| gaaagattta ccatctgaaa | ctgttaaaaa | tcttgaaagc         | aagttatcaa | aacaagagag | 1260             |
| tgtttcacac actttaactg | ctaaaaaaga | aaatgttgct         | cctcgtgacc | aagaatttta | 1320             |
| tgataaagca tataatctgt | taactgaggc | tcataaagcc         | ttgtttgnaa | ataagggtcg | 1380             |
| taattctgat ttccaagcct | tagacaaatt | attagaacgc         | ttgaatgatg | aatcgactaa | 1440             |
| taaagaaaaa ttggtagatg | atttattggc | attcctagca         | ccaattaccc | atccagagcg | 1500             |
| acttggcaaa ccaaattctc | aaattgagta | tactgaagac         | gaagttcgta | ttgctcaatt | 1560             |
| agctgataag tatacaacgt | cagatggtta | catttttgat         | gaacatgata | taatcagtga | 1620             |
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| cctttctgat aaggaaaaag | ttgcagctca | agcctatact         | aaagaaaaag | gtatcctacc | 1740             |
| tccatctcca gacgcagatg | ttaaagcaaa | tccaactgga         | gatagtgcag | cagctattta | 1800             |
| caatcgtgtg aaaggggaaa | aacgaattcc | actcgttcga         | cttccatata | tggttgagca | 1860             |
| tacagttgag gttaaaaacg | gtaatttgat | tattcctcat         | aaggatcatt | accataatat | 1920             |
| taaatttgct tggfttgatg | atcacacata | caaagctcca         | aatggctata | ccttggaaga | <sup></sup> 1980 |
| tttgtttgcg acgattaagt | actacgtaga | acaccctgac         | gaacgtccac | attctaatga | 2040             |
| tggatggggc aatgccagtg | agcatgtgtt | aggcaagaaa         | gaccacagtg | aagatccaaa | 2100             |
| taagaacttc aaagcggatg | aagagccagt | agaggaaaca<br>Page | cctgctgagc | cagaagtccc | 2160             |
|                       |            | rage               | -          |            |                  |

#### 340-SL-12-Dec-02

| ·  |
|--|
| tcaagtagag actgaaaaag tagaagccca actcaaagaa gcagaagttt tgcttgcgaa              |
| agtaacggat tctagtctga aagccaatgc aacagaaact ctagctggtt tacgaaataa              |
| tttgactctt caaattatgg ataacaatag tatcatggca gaagcagaaa aattacttgo              |
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| <220>  |
| <221> SITE   |
| <222> (456)(456)   |
| <223> Xaa equals any naturally ocurring amino acid                             |
|  |
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| 1 5 10 15  |
| Arg Val Ser Tyr Ile Asp Gly Lys Gln Ala Thr Gln Lys Thr Glu Asn<br>20 25 30    |
| Leu Thr Pro Asp Glu Val Ser Lys Arg Glu Gly Ile Asn Ala Glu Gln<br>35 40 45    |
| Ile Val Ile Lys Ile Thr Asp Gln Gly Tyr Val Thr Ser His Gly Asp<br>50 55 60    |
| His Tyr His Tyr Tyr Asn Gly Lys Val Pro Tyr Asp Ala Ile Ile Ser<br>65 70 75 80 |
| Glu Glu Leu Leu Met Lys Asp Pro Asn Tyr Lys Leu Lys Asp Glu Asp                |

Tyr Tyr Val Tyr Leu Lys Asp Ala Ala His Ala Asp Asn Val Arg Thr 115 120 125

Ile Val Asn Glu Val Lys Gly Gly Tyr Val Ile Lys Val Asp Gly Lys
100 105 110

#### Lys Glu Glu Ile Asn Arg Gln Lys Gln Glu His Ser Gln His Arg Glu 130 135 140

Gly Gly Thr Pro Arg Asn Asp Gly Ala Val Ala Leu Ala Arg Ser Gln 145 150 155 160

Gly Arg Tyr Thr Thr Asp Asp Gly Tyr Ile Phe Asn Ala Ser Asp Ile 165 170 175

340-SL-12-Dec-02 Ile Glu Asp Thr Gly Asp Ala Tyr Ile Val Pro His Gly Asp His Tyr 180 185 190 His Tyr Ile Pro Lys Asn Glu Leu Ser Ala Ser Glu Leu Ala Ala 195 200 205 Glu Ala Phe Leu Ser Gly Arg Gly Asn Leu Ser Asn Ser Arg Thr Tyr 210 215 220 Arg Arg Gln Asn Ser Asp Asn Thr Ser Arg Thr Asn Trp Val Pro Ser 225 230 235 240 Val Ser Asn Pro Gly Thr Thr Asn Thr Asn Thr Ser Asn Asn Ser Asn 245 250 255 Thr Asn Ser Gln Ala Ser Gln Ser Asn Asp Ile Asp Ser Leu Leu Lys 260 270 Gln Leu Tyr Lys Leu Pro Leu Ser Gln Arg His Val Glu Ser Asp Gly 275 280 285 Leu Val Phe Asp Pro Ala Gln Ile Thr Ser Arg Thr Ala Arg Gly Val 290 295 300 Ala Val Pro His Gly Asp His Tyr His Phe Ile Pro Tyr Ser Gln Met 305 310 315 320 Ser Glu Leu Glu Glu Arg Ile Ala Arg Ile Ile Pro Leu Arg Tyr Arg 325 330 335 Ser Asn His Trp Val Pro Asp Ser Arg Pro Glu Gln Pro Ser Pro Gln 340 345 350 Pro Thr Pro Glu Pro Ser Pro Gly Pro Gln Pro Ala Pro Asn Leu Lys 355 360 365 Ile Asp Ser Asn Ser Ser Leu Val Ser Gln Leu Val Arg Lys Val Gly 370 380 Glu Gly Tyr Val Phe Glu Glu Lys Gly Ile Ser Arg Tyr Val Phe Ala 385 390 395 400 Lys Asp Leu Pro Ser Glu Thr Val Lys Asn Leu Glu Ser Lys Leu Ser 405 410 415 Lys Gln Glu Ser Val Ser His Thr Leu Thr Ala Lys Lys Glu Asn Val 420 425 430 Ala Pro Arg Asp Gln Glu Phe Tyr Asp Lys Ala Tyr Asn Leu Leu Thr 435 440 445 Glu Ala His Lys Ala Leu Phe Xaa Asn Lys Gly Arg Asn Ser Asp Phe 450 455 460 Lys Glu Lys Leu Val Asp Asp Leu Leu Ala Phe Leu Ala Pro Ile Thr 485 490 495 His Pro Glu Arg Leu Gly Lys Pro Asn Ser Gln Ile Glu Tyr Thr Glu 500 505 510

340-SL-12-Dec-02 Asp Glu Val Arg Ile Ala Gln Leu Ala Asp Lys Tyr Thr Thr Ser Asp 515 520 525 Gly Tyr Ile Phe Asp Glu His Asp Ile Ile Ser Asp Glu Gly Asp Ala 530 540 Tyr Val Thr Pro His Met Gly His Ser His Trp Ile Gly Lys Asp Ser 545 550 555 560 Leu Ser Asp Lys Glu Lys Val Ala Ala Gln Ala Tyr Thr Lys Glu Lys 565 570 575 Gly Ile Leu Pro Pro Ser Pro Asp Ala Asp Val Lys Ala Asn Pro Thr 580 585 590 Gly Asp Ser Ala Ala Ile Tyr Asn Arg Val Lys Gly Glu Lys Arg 595 600 605 Ile Pro Leu Val Arg Leu Pro Tyr Met Val Glu His Thr Val Glu Val 610 615 620 Lys Asn Gly Asn Leu Ile Ile Pro His Lys Asp His Tyr His Asn Ile 625 630 635 640 Lys Phe Ala Trp Phe Asp Asp His Thr Tyr Lys Ala Pro Asn Gly Tyr 645 650 655 Thr Leu Glu Asp Leu Phe Ala Thr Ile Lys Tyr Tyr Val Glu His Pro 660 665 670 Asp Glu Arg Pro His Ser Asn Asp Gly Trp Gly Asn Ala Ser Glu His 675 680 685 Val Leu Gly Lys Lys Asp His Ser Glu Asp Pro Asn Lys Asn Phe Lys 690 695 700 Ala Asp Glu Glu Pro Val Glu Glu Thr Pro Ala Glu Pro Glu Val Pro 705 710 715 720 Gln Val Glu Thr Glu Lys Val Glu Ala Gln Leu Lys Glu Ala Glu Val 725 730 735 Leu Leu Ala Lys Val Thr Asp Ser Ser Leu Lys Ala Asn Ala Thr Glu 740 745 750 Thr Leu Ala Gly Leu Arg Asn Asn Leu Thr Leu Gln Ile Met Asp Asn 755 760 765 Asn Ser Ile Met Ala Glu Ala Glu Lys Leu Leu Ala Leu Leu Lys Gly 770 780 <u>Ser Asn Pro Ser Ser Val Ser Lys Glu Lys Ile</u> 785 790 795

<210> 3

<211> 37

<212> DNA

<213> Artificial Sequence

<220>

#### <223> PCR primer

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|------------------|---|----|
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| <212>            | DNA                                       |    |
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| <220>            |   |    |
| <223>            | PCR primer                                |    |
| <400><br>agtcaag | 4<br>gctt gtttatttt tccttactta cagatgaagg | 40 |

